

PRESIDENT'S MALARIA INITIATIVE

Malaria Operational Plan (MOP)

KENYA

FY 2008

TABLE OF CONTENTS

Abbreviations	4
Executive Summary	5-7
Description of the President's Malaria Initiative	8
Country Background	9-10
Government Health System	11-13
The Global Fund to Fight AIDS, Tuberculosis, & Malaria	13-14
Malaria Situation and Funding	14-15
Current Status of Malaria Control	15-16
Current Status of Malaria Indicators	17
Goal and Targets of the President's Malaria Initiative	18
Expected Results Year One	18-19
Interventions	
Malaria in Pregnancy	19-22
Insecticide-Treated Bed Nets	22-25
Indoor Residual Spraying	25-27
Case Management	27-33
Epidemic Preparedness and Response	33-35
Surveillance, Monitoring and Evaluation	35-37
HIV/AIDS and Malaria	37-39
Capacity Building within the National Malaria Control Program	39-40
Communication and Coordination	40
NGO Collaboration	40-41
Staffing and Administration	41-42
Annex 1	
Table 1	43-45
Table 2	46-48
Table 3	49-50
Table 4	51
Table 5	52
TDY Plan	53

Annex 2: Kenya PM	II Three-Year	Strategy	54-	-60
-------------------	---------------	----------	-----	-----

ABBREVIATIONS

ACT Artemisinin-based combination therapy

ANC Antenatal clinic

AL Artemether-lumefantrine

AQ/SP Amodiaquine/sulfadoxine-pyrimethamine

ARV/ART Anti-retroviral/therapy

BCC Behavior change communications CCM Country Coordinating Mechanism

CDC Centers for Disease Control and Prevention
CSHGP Child Survival and Health Grants Program
DfID Department for International Development (UK)

DHS Demographic and Health Survey
DOMC Division of Malaria Control
FBO Faith-based organization

GFATM Global Fund to Fight AIDS, Tuberculosis, and Malaria

GOK Government of Kenya

HMIS Health Management Information Service
IMCI Integrated Management of Childhood Illnesses
IPTp Intermittent preventive treatment of pregnant women

IRS Indoor residual spraying ITN Insecticide-treated bed net

KEMRI Kenya Medical Research Institute KEMSA Kenya Medical Supply Agency

LLIN Long-lasting insecticide-treated bed net

MCH Maternal and child health

MEDS Mission for Essential Drug Supply

MERG Roll Back Malaria Monitoring and Evaluation Reference Group

MIP Malaria in pregnancy
MOH Ministry of Health
MOP Malaria Operational Plan
NGO Non-governmental organization

PEPFAR President's Emergency Plan for AIDS Relief

PLWHA People living with HIV/AIDS PMI President's Malaria Initiative

PMTCT Prevention of mother-to-child transmission

PSI Population Services International

RBM Roll Back Malaria
RDT Rapid diagnostic test
RTI Research Triangle Institute

USAID United States Agency for International Development

WRAIR Walter Reed Army Institute of Research

EXECUTIVE SUMMARY

Kenya has been selected as one of the eight new countries to receive funding during the third year of the President's Malaria Initiative (PMI). The objective of this Initiative is to assist African countries, in collaboration with other partners, to rapidly scale-up coverage of vulnerable groups with four highly effective interventions: artemisinin-based combination therapy (ACT), intermittent preventive treatment for malaria in pregnancy (IPTp), insecticide-treated mosquito nets (ITNs), and indoor residual spraying (IRS) with residual insecticides.

Malaria is the leading cause of morbidity and mortality in Kenya. It accounts for about 30% of all outpatient consultations, 19% of all hospital admissions, and is reported to cause approximately 34,000 deaths among children under-five years of age. Kenya has 30 malaria-endemic districts where malaria transmission is stable and takes place year round with two peak transmission periods (June-August, and late November). In addition, there are 16 districts with seasonal transmission at risk of epidemics. The total population at risk of malaria is approximately 23 million, or 70% of the population, including an estimated 3,500,000 children under five and 1,100,000 pregnant women.

According to the most recent Demographic and Health survey (DHS) conducted in 2003, only 6% of children under five with fever received first-line treatment for malaria within 24 hours, and only 4% of pregnant women received any kind of treatment during their pregnancy. In late 2006, the Centers for Disease Control and Prevention (CDC) conducted a population-based survey in six provinces with a high burden of malaria. The survey results showed that approximately 36% of pregnant women and 52% of children under five had slept under an ITN the previous night, up from 4.4% and 4.6% respectively in the 2003 DHS, and after a 2006 campaign that distributed ITNs in these districts. IRS was conducted in 2006 and 2007 in 16 epidemic-prone districts with seasonal transmission, but the proportion of households covered is not known. No up-to-date information exists on national or provincial coverage with ACTs or IPTp. A Malaria Indicator Survey, representative of malarious areas nationally, was conducted according to Roll Back Malaria Monitoring and Evaluation Reference Group (MERG) methodology in 2007 and results are pending.

The Government of Kenya subscribes to the Roll Back Malaria Abuja targets and the Millennium Development Goals. Malaria is considered a priority for poverty reduction and the government's development agenda. Although the Ministry of Health (MOH) is committed to increasing access to health services and increasing the efficiency and quality of those services nationwide, a weak health infrastructure and shortage of health workers are formidable obstacles. In 2005, Kenya adopted a sector-wide approach for health, led by the MOH and with the participation of bilateral and multilateral agencies.

Kenya is the recipient of two malaria grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria totaling \$213,796,930 million. The Department for International Development (DfID) has been the major bilateral supporter of malaria programs in Kenya, providing approximately \$20 million each year to support social marketing of ITNs and providing technical assistance to the Division of Malaria Control (DOMC) through the World Health Organization. The US Government has a long-standing presence in Kenya working in malaria research and

control through USAID, CDC, and the Walter Reed Army Institute of Research (WRAIR). With support from these organizations, as well as UNICEF, and other national and international partners, a scaling up of malaria prevention and control interventions has already started.

This PMI Year 1 MOP for Kenya was developed in close consultation with the DOMC and with participation of nearly all national and international partners involved with malaria prevention and control in the country. The activities that the PMI is proposing to support fit in well with the Ministry of Health National Malaria Strategic Plan and build on investments made by the DOMC, USAID, CDC, and other donors to improve and expand malaria-related services over the past several years. To achieve the goal and targets of the MOH/NMCC and PMI in Kenya, the following major activities will be supported during Year 1 of the initiative:

Insecticide-treated nets: Kenya has used several service delivery mechanisms over the last five years to distribute almost 11 million nets including: free/highly-subsidized ITNs provided through antenatal care (ANC) clinics, routine and campaign expanded program on immunization (EPI) services, child health action days, community-based initiatives and retail outlets. The DOMC set a target of 80% coverage of vulnerable groups by 2007, defined as children under-5 and pregnant women. To support this target, in Year 1 the PMI will procure 600,000 LLINs for highly subsidized distribution through ANCs, and 50,000 to support the DfID funded, WHO retreatment/replacement campaign. Other partners will procure approximately 2.4 million ITNs; the combined effort is expected to bring nationwide ownership of target groups to 65%. While coverage has increased dramatically over the last several years, usage remains low; therefore, PMI will work with non-governmental organizations (NGOs) to support community-based information, education and communication/behavior change communication (IEC/BCC) campaigns to increase demand for and correct usage of LLINs.

Indoor residual spraying: Kenya began spraying in 16 seasonal transmission districts in 2007 with support from GFATM Round 4 funding. Under the PMI, the USG will continue to support IRS activities in two of these 16 districts, as well as two bordering endemic districts to support the MOH strategy of transitioning IRS activities into endemic areas. PMI will procure insecticides and other IRS-related commodities and contributing to operational costs, in addition to training and supervision of sprayers and supervisors, support for enhanced surveillance and insecticide resistance monitoring, and IEC/BCC. These activities will support the DOMC strategy of targeting one million households in 2008, protecting approximately five million people.

Intermittent preventive treatment of pregnant women: Despite high attendance of antenatal clinics (ANC) the 2003 DHS showed substantially low coverage of IPTp. In order to increase demand for IPTp, in Year 1 the PMI will support strengthening of focused antenatal care (FANC) in districts where training and community-based and nationwide IEC/BCC efforts have been limited. In addition, PMI will support the procurement of 840,000 doses of sulfadoxine-pyremethamine (SP) to complement the 280,000 doses being procured by GFATM Round 2, to achieve 50% coverage of pregnant women with two doses of IPTp.

<u>Case management</u>: There are currently no written national policy guidelines for malaria diagnosis, although the DOMC promotes the use of presumptive diagnosis in children under-5,

and in others when laboratory confirmation is not available. The MOH expressed a desire to expand microscopic diagnosis and further explore the use of rapid diagnostic tests (RDTs), which are not currently widely-used in Kenya. To support efforts to increase diagnostic capacity and quality, PMI in Year 1 will support the training of 80 laboratory technicians, as well as procure 80 microscopes for the facilities where they work. While WHO and DfID are supporting the development of a national strategy for laboratory diagnosis of malaria, PMI will support a baseline needs assessment of diagnostic capacity to identify gaps. PMI will also support an RDT pilot evaluation in two districts of health care worker compliance with results of the RDTs to provide the MOH additional information to guide the possible roll-out of RDTs to all districts. PMI will procure ACTs and drugs for severe malaria and will invest in strengthening the supply chain and logistics systems for malaria drugs to ensure reliable access and a steady supply of these essential antimalarial medications. To ensure that ACTs are properly used and improve the quality of malaria treatment, PMI will support training and supervision at the health facility level, and preservice training of health care providers. Finally, PMI will support increased demand for and correct use of ACTs through national and community-based IEC/BCC activities. Combined with the investment from the GFATM, PMI support in this area is expected to result in over 40% of children under five in Kenya receiving ACTs by the end of Year 1.

Monitoring and evaluation: The PMI includes a strong monitoring and evaluation component to measure progress against the project goal and targets and identify and correct problems in program implementation. The PMI monitoring and evaluation plan will be coordinated with the DOMC to ensure that critical gaps are being filled, and to standardize data collection and reporting. In the first year, PMI will provide support to strengthening the health information system, including the printing and dissemination of registers, support sentinel sites, establish methods in demographic surveillance sites (DSS) to investigate causes of deaths for deaths at health facilities relative to routine surveillance, and support the malaria portion of the 2008 DHS including verbal autopsy.

<u>Building NMCP capacity</u>: To achieve PMI targets for coverage of ACTs, ITNs, IPTp, and IRS, the PMI will work with other partners to strengthen the capacity of the MOH/DOMC at the central, provincial, and district levels to plan, conduct, supervise, monitor and evaluate malaria prevention and control activities. Efforts will also be directed at improving coordination/communication between the MOH/DOMC and partners.

To launch the PMI in Kenya, support will be provided with Fiscal Year (FY) 2008 funding to the roll-out of ACT and malaria in pregnancy (MIP) training in targeted districts where this has not yet taken place.

The proposed FY08 PMI budget for Kenya is \$20 million. Of this amount, 29% will support procurement and distribution of ITNs, 31% improved case management including the purchase of ACTs and drugs for severe malaria, and 20% IRS. Just over 6% will support malaria in pregnancy activities, and 5% will support monitoring and evaluation. Approximately 50% of the total budget will be spent on commodities.

THE PRESIDENT'S MALARIA INITIATIVE

In June 2005, the United States Government (USG) announced a new five-year, \$1.2 billion initiative to rapidly scale-up malaria prevention and treatment interventions in high-burden countries in sub-Saharan Africa. The goal of this Initiative is to reduce malaria-related mortality by 50% after three years of full implementation in each country. This will be achieved by reaching 85% coverage of the most vulnerable groups---children under five years of age and pregnant women ---with proven preventive and therapeutic interventions, including artemisinin-based combination therapies (ACTs), insecticide-treated bed nets (ITNs), intermittent preventive treatment (IPTp) of pregnant women, and indoor residual spraying (IRS).

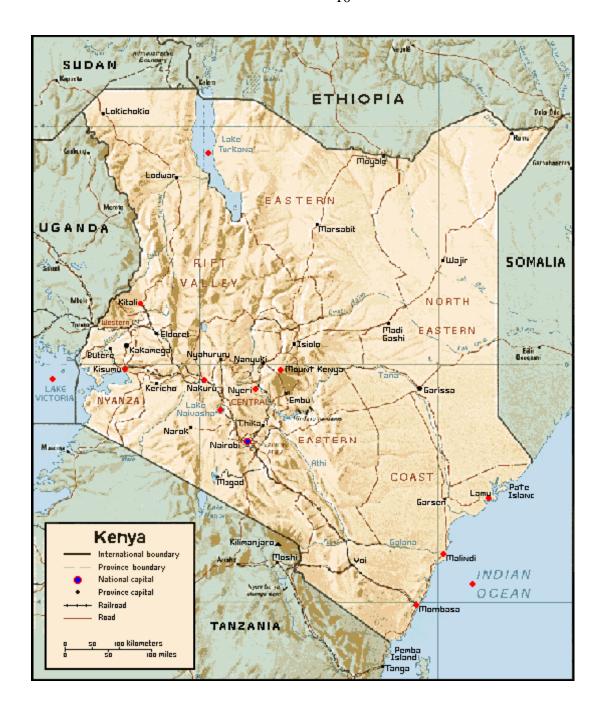
The President's Malaria Initiative (PMI) began in three countries in 2006: Angola, Tanzania, and Uganda. In 2007, four countries were added: Malawi, Mozambique, Senegal, and Rwanda. In December, 2006, at the Malaria White House Summit, the 2008 countries were announced: Benin, Ethiopia (one region), Ghana, Kenya, Liberia, Madagascar, Mali, and Zambia. Funding began with \$30 million in Fiscal Year (FY) 06 for the initial three countries, increased to \$160 million in FY 07, and will rise to \$300 million in FY 08, and reach \$500 million in FY 10.

In implementing the U.S. Government component of this Initiative, the PMI is committed to working closely with host governments and within existing national malaria control plans. Efforts will be coordinated with other national and international partners, including the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM), Roll Back Malaria (RBM), the World Bank Malaria Booster Program, World Health Organization (WHO), the United Nations Children's' Fund (UNICEF), and the non-governmental and private sectors, to ensure that investments are complementary and that RBM and Millennium Development Goals are achieved. Country Assessment and Planning sessions for the PMI, as well as subsequent evaluations, will be highly consultative and held in collaboration with the National Malaria Control Program and other partners.

In Kenya, a needs assessment was conducted from February 12-23, 2007, and consisted of meetings with the Division of Malaria Control (DOMC) and other partners to identify current activities and gaps. Results of the needs assessment were used to guide the planning visit from April 23-May 1, 2007. During this visit, members of the PMI team met with the DOMC to identify priorities for funding for FY08, guided in part by a stakeholders meeting with partners involved in malaria control. This document presents that detailed one-year implementation plan for the first year of the PMI in Kenya. It briefly reviews the current status of malaria control and prevention policies and interventions, identifies challenges and unmet needs if the goals of the PMI are to be achieved, and provides a description of planned Year One activities under the PMI. The document was developed in close consultation with the National Malaria Control Program and with participation of many national and international partners involved in malaria prevention and control in the country. The total amount of PMI funding requested for Kenya is \$20 million for FY 2008.

COUNTRY BACKGROUND

Kenya has a population of approximately 34 million with an annual growth rate of 2.3%, and is geographically divided into 8 provinces and 72 districts. The country falls into two main regions: lowland areas, both coastal and around lake basins, and highland areas on both sides of the Great Rift Valley. The country has approximately 42 ethnic groups, and is a predominantly agricultural economy with a strong industrial base. Kenya ranked 152 out of 177 countries on the 2006 United Nation's Human Development Index which measures life expectancy, adult literacy and per capita income. Life expectancy in Kenya has seen an overall downward trend since the late 1980s, but has recently increased to 51 years; HIV/AIDS overall adult prevalence was 7.4% percent in 2004 (World Health Organization); the national primary school enrollment level is nearly 80 percent; and gross national income per capita is less than \$1200 USD. In 2004, the total expenditure on health represented 4.1 percent of the GDP, but the MOH plans to increase this to 8.4% of in 2007/8. The total fertility rate dramatically decreased between the 1970s and mid-1990s, but has recently been on the rise, currently at 5.0 children per woman. Furthermore, more than one in ten children dies before the age of five, with malaria being the number one child killer.



HEALTH SYSTEMS INFRASTRUCTURE AND HEALTH SERVICE DELIVERY

There is considerable policy commitment on the part of the Government of Kenya (GOK) to improve health service delivery as well as a commitment to malaria control. This is reflected in several key policy documents, including the National Health Sector Strategic Plan II, 2005-2010 (NHSSP II), the National Malaria Strategic Plan, and the Division of Malaria Control Annual Operational Plan II. The vision of the NHSSP II is to provide an efficient and high quality health care system that is accessible, equitable, and affordable for every Kenyan. As part of this, the Kenya Essential Package for Health represents the integration of all health programs into a single package that focuses its interventions on the improvement of health at different phases of the human development cycle and through service delivery at six different levels of the health care system. Malaria prevention and treatment is a key component of the Kenya Essential Package for Health.

In order to address the increasing problem of morbidity and mortality due to malaria, the GOK has made malaria a high priority for prevention and treatment under the DOMC. In 2001, the government developed a 10-year National Malaria Strategy with the main objective to reduce the level of malaria illness and death in Kenya by 30% and to sustain that improved level of control until 2010. The National Malaria Strategy directly contributes to the Millennium Development Goals on reducing child mortality and maternal mortality.

The National Malaria Strategy articulates four strategic approaches that will:

- Guarantee all people access to quick and effective treatment;
- Provide malaria prevention measures and treatment to pregnant women;
- Ensure the use of ITNs by at-risk communities; and
- Improve epidemic preparedness and response in epidemic-prone areas.

In addition, in January, 2005, the DOMC developed a Malaria Communication Strategy to support the scaling up of effective interventions and targets outlined in the National Malaria Strategy. The plan describes communication issues and broad information, education, and communication (IEC) approaches in support of the four National Malaria Strategy strategic approaches, including prompt and effective treatment; management of malaria in pregnancy; ITN distribution and other vector control methods; and epidemic preparedness and response. An IEC technical working group comprising representatives from various departments of the MOH and stakeholders was formed to assist in the implementation of the plan.

Formal Health Facilities and Providers

There are six service delivery levels defined in the Kenya Essential Package for Health:

- Level 1, the community level;
- Levels 2 and 3, the dispensaries, health centers and maternity/nursing homes, which primarily handle promotive and preventive care, but also some curative services; these facilities provide the bulk of health care services; and
- Levels 4-6, the primary, secondary, and tertiary hospitals, which focus mainly on the curative and rehabilitative aspects of the service delivery package.

In 2003, there were approximately 4,557 health facilities (526 hospitals, 649 health centres, and 3,382 health sub-centres and dispensaries). About 51% of these were MOH facilities, with 20% managed by non-governmental organizations/faith-based organizations (NGOs/FBOs) and 29% managed by the private sector. The MOH indicates that the proportion of public sector health facilities has risen to approximately 58%. The largest private health care providers in Kenya are the African Medical and Research Foundation, the Christian Health Associations of Kenya, the Kenya Catholic Secretariat, the Family Planning Association of Kenya, the Kenya AIDS NGO Consortium, and the Kenyan Aga Khan Foundation.

The lack of health professionals remains one of the greatest challenges facing the health sector. In 2003, there were 4,813 physicians (15.3/100,000 population) and 9,869 registered nurses (33.1/100,000 population) working in the public sector, which constitutes approximately 70% of all health personnel in Kenya. While the population to nurse ratio is within the WHO norm of 5,000 per nurse, and the population to doctor ratio is within the WHO norm of 10,000 per physician, these figures hide the large disparity in population to provider ratios among districts and between rural and urban areas. In 2004, human resource mapping and verification study (MOH, December 2004) found that 47% of dispensaries had just one community nurse and one or two support staff, while 3% had only support staff not qualified to administer drugs. Provincial and district hospitals were found to be overstaffed with nurses, and there was a discrepancy in the staffing of doctors at district hospitals, with about half having fewer than 6 (12 required), while others had more than 20.

The Health Sector Report 2007 notes that the MOH currently has 37,868 employees and aims to increase that to 42,154. Furthermore, USAID and the Clinton Foundation have supported the recruitment of 1,154 contract health workers. In order to enhance the efficiency of health services the GOK intends to further decentralize its financial operations and disburse funds directly to health facilities. A Health Facility Fund will be established to implement this process and provide stringent criteria for the use of cost share funds at the facilities. These facilities include MOH facilities and about 600 dispensaries built utilizing the Constituency Development Fund (CDF), a financial mechanism controlled by Members of Parliament.

Management and Organization

While in the past, the central MOH has acted on an operational level to implement and manage the provision of health services, under the current health reforms the central MOH will act more to oversee, govern and facilitate, while passing on more responsibility for service provision to the provincial and district health management teams (DHMTs). The MOH has made efforts to promote this decentralization by having DHMTs set local priorities and manage all health activities.

Community Health Providers

The National Health Sector Strategic Plan of Kenya (NHSSP II-2005-2010) outlines the implementation of community health services as the top priority of the ministry of health (MOH) and its development partners. The plan establishes quotas of community-owned resource persons (CORPs) and Community Health Extension Workers (CHEWs) covering specific areas,

their terms of reference, and budgetary implications. It envisions the capacity of households to demand services from all providers by knowing and progressively realizing their rights.

Community-owned resource persons communicate health messages and mobilize their communities, and promote utilization of health services. The MOH has advocated a system where one CORP will serve 20 households or 100 people, and be supervised by a CHEW, linking the community to the health system. Each CHEW would supervise 50 CORPs. This system has not yet been scaled-up.

The MOH has placed a high priority on their community strategy, designed to "ensure that Kenyan communities have the capacity and motivation to take up their essential role in health care delivery". This strategy provides part of the framework for action within recommended PMI interventions, particularly with regard to training for malaria in pregnancy and treatment protocols, use of community-based NGOs for improving ITN use practices and IRS.

THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS, AND MALARIA

Kenya currently has two Global Fund grants for malaria, one from Round 2 and one from Round 4. According to the Global Fund Grant Performance Report, although there were some initial delays, the potential for progress is good. For Round 2, phase 1 and phase 2 have been approved releasing the grant total of \$27,700,377. Of this amount, \$4,640,447 has been disbursed. The Round 4 grant totals \$186,096,553. Phase 1 totaling \$81,749,756 has been approved, and \$52,188,969 disbursed. The DOMC is currently finalizing reports necessary to begin the request for Phase 2 approval.

The Round 2 grant objectives include:

- 1. Increasing the percentage of pregnant women and children under five sleeping under ITNs through an ITN distribution system and community awareness campaign
- 2. Increasing the percentage of pregnant women accessing IPTp with SP, including the purchase of SP
- 3. Improving case management and effective treatment through training in Integrated Management of Childhood Illnesses and training shopkeepers in appropriate drug dispensing practices,
- 4. Improving community access to information about malaria through IEC and setting up ITN advocacy groups.

The Round 4 grant is a five-year grant (2006-2011) that includes:

- 1. Purchase and distribution of artemether-lumefantrine (AL; Coartem®) (pediatric and adult doses) as well as training of health workers to implement the new drug policy. Under this grant, Kenya should be able to cover or nearly cover ACT needs through all five years of the grant;
- 2. Reduce morbidity and mortality due to epidemics through a) establishment of an early epidemic warning system and epidemic detection and response systems; b) conducting indoor residual spraying in high risk areas; and c) improving management of malaria cases in epidemic situations;

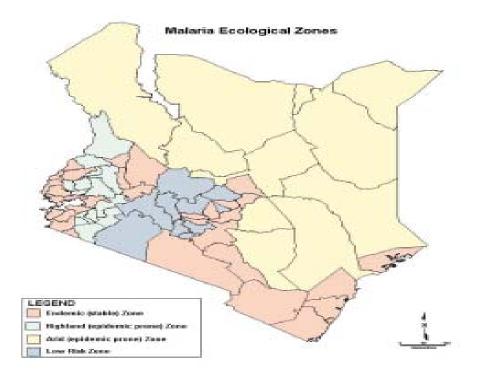
¹ "Taking the Kenya Essential Package for Health to the Community", Kenya Ministry of Health, June 2006.

- 3. Procurement and distribution of LLINs to children under five and pregnant women to reach targets of 80% of children under five and 70% of pregnant women sleeping under an ITN;
- 4. Improve community participation in malaria prevention and treatment;
- 5. Build capacity for effective implementation through developing human resources; strengthening health management systems; improving coordination and partnership among all implementers; strengthening monitoring and evaluation; strengthening drug supply and stock management at the health facility level

MALARIA SITUATION IN KENYA

Malaria is the leading cause of morbidity and mortality in Kenya, and over 70% of Kenyans (approximately 23 million people) are at risk of malaria infection. Malaria is responsible for approximately 30% of outpatient visits requiring more than 8 million out-patient treatments at health facilities each year, and 19% of all hospital admissions. Children under-five are particularly vulnerable, and about 3.5 million are at risk of infection and the development of severe malaria, which not only affects child survival, but educational and social developmental delay as well. At least 14,000 children are hospitalized annually for malaria, and there are an estimated 34,000 deaths among children under five each year. Pregnant women are also at high risk, and there are approximately 1.1 million pregnancies per year in malaria endemic areas. During pregnancy, malaria causes anaemia, miscarriages and can result in low birth weight babies. Each year, an estimated 6,000 pregnant women suffer from malaria-associated anaemia, and four thousand babies are born with low birth weight as a result of maternal anaemia. Economically, it is estimated that 170 million working days are lost each year because of malaria illness.

Kenya has four malaria epidemiological zones: endemic areas along the shores of Lake Victoria and the south coast where malaria transmission is perennial; epidemic-prone areas in highlands, which are highly populated and where transmission is seasonal; epidemic-prone areas where transmission is seasonal and arid/semi-arid lowlands, which are sparsely populated; and highlands around mountainous areas with very low risk or no transmission. Transmission in the epidemic-prone/seasonal areas is highest from April through June.



CURRENT STATUS OF MALARIA CONTROL

The 2003 Demographic and Health Survey (DHS) showed weak case management practices for malaria in children under-five years of age. Among those reporting a fever in the two weeks before the survey, only 26.5% had taken an antimalarial drug and only 11.1% had taken it the same or next day. Children under 6 months of age were less likely to receive antimalarial drugs. Overall, 11% and 10% of children with fever and/or convulsions took the first-line, sulfadoxine-pyrimethamine (SP), or second-line (amodiaquine) drug, respectively, and only 6% and 5% received those drugs within 24 hours of the onset of illness. Approximately 4% of children were given quinine, reserved for severe malaria, and 70% took only non-antimalarial drugs. Only 3% were given chloroquine, which had been taken off the market in 1998.

Use of preventive measures is also inadequate, although there has been some recent progress in the coverage and use of insecticide-treated bednets (ITNs). The 2003 DHS reported that 22% of households in Kenya owned a bed net of any type, with only 6% owning an ITN. Only 4.6% of children under five had slept under an ITN the previous night. The Division of Malaria Control (DOMC) estimates that since 2002, approximately 10.8 million nets have been distributed through various mechanisms, although they estimate that 40% of these were conventional, untreated nets (the DOMC estimates that one-quarter of those conventional nets have subsequently been treated in the last 12 months). A survey conducted by CDC in late 2006 in 6 provinces with the highest malaria burden in Kenya indicated that 66.9% of households owned any net, and 50.7% owned an ITN, which could include either a long-lasting ITN (LLIN) or any net treated in the last 12 months. Approximately 51.7% of children under five had slept under an

ITN the previous night. While these numbers have improved since 2003, they remain below national targets for coverage and use.

Only 4.4% (n=647) of pregnant women had slept under an ITN the previous night in the 2003 DHS survey. This number increased to 36.3% in the CDC survey, although the sample size was small and representative of only six provinces with highest malaria risk(n=182). For women reporting a birth during the previous five years, only 4.0% had taken any antimalarial drug during the pregnancy. Among women who received treatment, almost 60% took SP and 24% of them took two doses.

The analysis of malaria-related funding in the DOMC Annual Operation Plan II showed a total malaria budget for 2005-7 of 8,362,126,881 Ksh (approximately \$123 million) for malaria control, treatment, and prevention, with donors, households, and public sources being the main financiers of malaria care. Over 78% through GFATM rounds 2 and 4, and 17% through the Department for International Development (DfID)/WHO with the remainder coming from UNICEF, USAID, the Government of Kenya (GOK), and other donors.

CURRENT AND PREVIOUS USG MALARIA ACTIVITES IN KENYA

U.S. Government

USAID and CDC have a long history of working on malaria in Kenya, and have worked together on malaria and HIV/AIDS during the last 15 years. Kenya is a President's Emergency Plan for AIDS Relief (PEPFAR) focus country with implementation through USAID and CDC as well as through Walter Reed.

CDC: CDC has worked in partnership with the Kenya Medical Research Institute (KEMRI) since 1979, supporting research related to malaria and other health issues. CDC has a research station in Kisumu in Nyanza Province, an area of very high malaria transmission, and has carried out several very important research studies including one of the definitive ITN studies in the late 1990s, major studies on the efficacy of IPTp, and studies on malaria and HIV. In addition to the Kisumu research station and the work with KEMRI, CDC also has a large presence in Kenya under PEPFAR.

USAID: USAID manages a comprehensive development assistance program including work in governance, natural resource management, and support for small farmers, education, and health and population. In addition to HIV/AIDS work under PEPFAR, USAID also supports work in reproductive health/family planning and infectious diseases, including tuberculosis and malaria. In malaria, USAID has worked with CDC on several research activities, and supported work in malaria in pregnancy. USAID also provided assistance to the DOMC in the transition to ACTs, including support for procurement, quantification, and quality assurance in complement to the GFATM's purchase of ACTs. USAID contributed to the DfID-supported program with Population Services International (PSI) to socially market ITNs and to sell highly-subsidized ITNs through antenatal clinics. USAID has also provided support to Management Sciences for Health to work with Kenya Medical Supply Agency (KEMSA) and the DOMC to improve the

management of drugs and to provide technical support to the Health Management Information System (HMIS).

Walter Reed: The Walter Reed Army Institute of Research has had a presence in Kenya for nearly 28 years, working with USAID, CDC, KEMRI and the Kenyan Ministry of Defense. The primary areas of work have included malaria vaccine and drug development, work in HIV/AIDS as well as other areas, including leishmaniasis. Walter Reed has a study site in Kombewa in Nyanza Province as well as a research laboratory in Kondele. Walter Reed runs a Center of Excellence for microscopy where they have trained research microscopists from throughout the African region. Walter Reed has helped develop the Nyanza Pediatric Hospital which has the potential for training. Currently Walter Reed also plays a role in PEPFAR, where they have 7,000 patients under treatment and provide care and support services for 8,000.

CURRENT STATUS OF MALARIA INDICATORS

Recent Estimates of Malaria Indicators: 2003 Kenya DHS			
Intervention	Estimates		
Proportion of children under five years old with fever in the	11.1%		
last two weeks who received treatment with an antimalarial			
according to national policy within 24 hours of onset of			
fever.			
Proportion of children under five years old with fever in the	6%		
last two weeks who received treatment with ACTs within			
24 hours of onset of fever.**			
Proportion of households with at least one ITN.	5.9%		
Proportion of children under five years old who slept under	4.6%		
an ITN the previous night.			
Proportion of pregnant women who slept under an ITN the	4.4%		
previous night			
Proportion of women who received two or more doses of	4%		
Intermittent preventive treatment (IPTp) during their last			
pregnancy in the last two years.			
Indoor residual spraying (IRS) (Proportion of targeted	50%		
houses adequately sprayed with a residual insecticide in the			
last 12 months)			
** MIS to be conducted in July 2007			
# Baseline data from DOMC estimates of 2006 IRS campaign			

The 2007 Kenya MIS (June-July 2007) will provide baseline data for the coverage indicators. The planned 2008 Kenya DHS will provide baseline data for all-cause under-five mortality.

GOAL AND TARGETS OF THE PRESIDENT'S MALARIA INITIATIVE (by 2010)

The goal of PMI is to reduce malaria-associated mortality by 50% compared to pre-Initiative levels in PMI countries. By the end of 2010, PMI will assist Kenya to achieve the following targets in populations at risk for malaria:

- More than 90% of households with a pregnant woman and/or children under five will own at least one ITN;
- 85% of children under five will have slept under an ITN the previous night;
- 85% of pregnant women will have slept under an ITN the previous night;
- 85% of houses in geographic areas targeted for IRS will have been sprayed;
- 85% of pregnant women and children under five will have slept under an ITN the previous night or in a house that has been sprayed with IRS in the last 6 months;
- 85% of women who have completed a pregnancy in the last two years will have received two or more doses of IPTp during that pregnancy;
- 85% of government health facilities have ACTs available for treatment of uncomplicated malaria; and
- 85% of children under five with suspected malaria will have received treatment with ACTs in accordance with national malaria treatment policies within 24 hours of onset of their symptoms.

EXPECTED RESULTS

By the end of Year 1, the PMI together with other partners will achieve the following key results:

Prevention:

- Procure and distribute a total of 3,050,000 LLINs (including 650,000 from PMI) to vulnerable groups through existing approaches (this should bring national household ownership of an ITN to approximately 65%);
- Provide 50,000 LLINs to replace torn or damaged nets as part of a retreatment/replacement campaign in collaboration with the DOMC, DfID and WHO
- Implement IRS campaigns in four districts, including two of the highland districts and two bordering endemic districts covering 250,000 households.

Treatment:

- Procure and assist with the distribution of 1.8 million treatments of AL (in terms of quantity of AL needed, this is expected to fill in the supply gap to treat 85% of children under 5 and older children).
- Fill two-thirds of the severe malaria drug and supply gap
- In collaboration with DfID, WHO, and the Global Fund resources, complete training for all facilities in the new malaria treatment policy
- Enhance laboratory capacity for microscopic diagnosis of malaria through provision of training and equipment

• Pilot RDTs in two districts in anticipation of nationwide roll out in PMI Year 2

Malaria in Pregnancy

• Complete training of health workers in IPTp in another 29 districts. This will complete IPTp training in 17 of the country's 46 districts with malaria transmission.

INTERVENTIONS – PREVENTION

Malaria in Pregnancy (MIP)

The MOH has adopted a Focused Antenatal Care (FANC) approach to promote the health of pregnant women, which includes a recommendation that pregnant women make at least four visits to a skilled provider during their pregnancy, beginning in the first trimester. Prevention of MIP has been incorporated as an integral component of the FANC approach. Each year approximately 1.6 million pregnancies occur in Kenya, with more than 1.1 million of those in women at risk of acquiring malaria infection. Kenya's MIP program is based on a close working the relationship between the Division of Reproductive Health (DRH) and the DOMC; the DRH manages program implementation while DOMC is responsible for technical oversight. The DOMC estimates that approximately 80-90% of women attend one antenatal clinic (ANC) visit, but that many of these visits occur late in pregnancy, often after the 27th week. The 2003 DHS estimated that 88% of women attend one ANC visit, 52% of women attend four ANC visits, and that the median month of pregnancy that women attended their first visit was 5.9 (23.6 weeks).

National policy for the prevention of MIP from the MOH's National Malaria Strategy, 2001-2010, calls for the provision of:

- Free treatment doses of SP at each ANC visit after the first trimester, not less than four weeks apart;
- Effective community-based communication to encourage prompt treatment of fever;
- Increased access to ITNs.

The policy for IPTp as worded in the 2006 National Guidelines for Diagnosis, Treatment, and Prevention of Malaria for Health Workers in Kenya is:

- Administer a dose of SP with each scheduled visit after quickening to ensure women receive at least two doses during pregnancy (nationwide).
- Women known to be HIV-infected or with unknown HIV status living in areas of high HIV prevalence (>10% among pregnant women) should receive at least three doses of IPTp.
- IPTp should be given at an interval of at least four weeks.
- Pregnant women who are HIV positive and are on daily cotrimoxazole chemoprophylaxis should not be given SP.

Despite the clarity of these guidelines, DOMC agrees that there is confusion among partners, within different divisions of the MOH, and among health care workers at all levels of the health care system as to correct practices. It was agreed that there is a need for a stakeholders meeting

on MIP with participation from the DOMC, DRH, provincial health managers, and other FBOs, NGOs, and private sector partners to clarify the correct policy, the reason for the change from a policy based on giving a dose during each trimester to giving a dose at each visit, and best practices. This stakeholder's meeting will be organized by WHO with support from DfID.

The MOH set targets to achieve by 2006 based on the Abuja targets, which have yet to be realized, including:

- 60% of women will have received two doses of SP for IPTp in the second and third trimester:
- 80% of fever or anemia cases will be appropriately managed at ANCs;
- 60% of pregnant women will sleep under an ITN

Current status of MIP interventions

Information on the proportion of pregnant women currently receiving one or two doses of IPTp is lacking. The current registries used at ANC clinics do not record the provision of IPTp. New registries have been developed that record IPTp 1, IPTp 2, and net use, but have not yet been printed and distributed to ANCs due to lack of funding. Data from the 2003 DHS indicate that approximately 4% of pregnant women received two doses of IPTp.

Funding for SP procurement is currently being undertaken through Phase 2 of the GFATM Round 2 grant, which began on October 1, 2003. In FY 2008 280,000 doses are being procured. The total number of doses needed to cover the approximately 1.1 million at risk pregnancies per year is about 2.2 million doses; assuming 100% coverage with at least two doses of SP during pregnancy, there is a shortfall of 1,920,000 doses. SP is currently distributed by KEMSA through essential drug kits to public health facilities, which are provided to hospitals every month, and to lower-level health facilities every three months. In Northeast and Coastal Provinces this is done on a demand-driven pull system, and in the other provinces as a push system with a fixed supply delivered at regular intervals. Anecdotally, stock-outs have been reported by staff of the DOMC and other partners, but the frequency and reason for the stock-outs is unclear as there is no reporting system in place to assess this. There is speculation by KEMSA that SP is being used for treatment due to shortages of AL. The Mission for Essential Drug Supply (MEDS) distributes SP to FBOs and some NGOs, and receives about 30% of the GFATM supply from KEMSA.

A cornerstone to the MOH's strategy, through DRH and DOMC to achieve the policy objectives is to provide FANC training at all levels of the health system, with a priority for MIP training in the 46 malaria-affected districts. FANC training includes prevention of mother-to-child transmission (PMTCT) of HIV, and the PMTCT group with PEPFAR is currently revising their guidelines to reflect the use of IPTp for MIP. Training and community reproductive health has been undertaken by the DRH with support from the DOMC as well as JHPIEGO, UNICEF, WHO, AMREF, the Population Council, and other organizations. On-going supervision is provided by the DHMTs. Training materials have been developed and training of health workers undertaken in at least 42 of the 46 endemic districts, of which 24 have been primarily through support from JHPIEGO. Many of these, however, were training-of-trainers at the district level with little training conducted at the dispensary or health center level. The DOMC would like to focus training for FANC/MIP and community reproductive health on four levels:

- Training of trainers from the District and Provincial Health Management Teams;
- Supervision training for members of the DHMT;
- Training of service providers; and
- Training of CORPs.

CORPs are perceived as essential to improve knowledge and create informed demand around uptake of IPTp, use of ITNs and early attendance at ANC. A service provision assessment (SPA) is planned for 2009 to evaluate health services, and will be used to evaluate health worker performance on the use of IPTp.

Some district-level surveys have been conducted where IPTp training has been implemented, showing much higher utilization rates of IPTp than in the 2003 Kenya DHS. For instance, JHPIEGO conducted a 2004 follow up survey to the trainings they conducted in 19 districts, demonstrating 77% of pregnant women receiving at least one dose of IPTp in four of the sampled districts. AMREF showed coverage of two doses of SP to increase from 13% in March 2003 in four districts to 53.3% in February 2006. CORPs were anecdotally observed to have a positive impact on community awareness and utilization rates in the three districts where they were trained, but actually IPTp coverage needs to be measured in these areas and compared with areas where CORPs have not been trained.

To expand FANC/MIP training to all levels of the health system and community in 34 malaria affected districts, the DOMC estimated a funding gap of approximately \$2.4 million. This includes training, the provision of training materials and registers to record use of IPTp and net use by pregnant women. WHO, with support from DfID, has agreed to expand FANC/MIP training to 17 districts in Nyanza and Western Provinces at the training of trainers (150 trained) and service providers (850 trained). The DOMC has now decided to target the 42 of the 46 malaria endemic districts that have developed work plans for MIP, but have not recalculated a total budget for these additional areas. In addition, they estimate a recurring cost of approximately \$625 every three months to support the CORPs in their community messaging activities.

A recent CDC survey showed the proportion of pregnant women sleeping under an ITN in 6 provinces involved in last years' GFATM supported free distribution of 3.4 million LLINs targeting children under 5 years of age to be 36%, although the sample size was small (n=182 pregnant women). LLINs (Supanet® Olyset®) are currently being supplied to 3,000 Maternal and Child Health and ANC clinics through PSI. Health facilities purchase the nets from PSI for 30 Ksh, (\$0.45) and sell them to beneficiaries for 50 Ksh (\$0.75). In addition, approximately 6,400 service providers have been trained in the use of LLINs to prevent malaria. This program has been supported by DfID from 2002-2007, and funding beyond this year is uncertain. It is estimated that at least one million nets are needed each year to keep up with the number new pregnancies and replacement nets. The Kenyan Red Cross Society and other partners are involved in community activities to increase net usage.

The first-line treatment for malaria in pregnancy is oral quinine in all three trimesters. The MOH recommends diagnosis by blood smear. The MOH also recommends that pregnant women receive ferrous sulfate (200mcg) and folic acid (5mg) at their second and third ANC visits, and

that signs and symptoms of anemia are evaluated during their first and fourth ANC visits. A clear policy must be articulated on the correct dosing of folic acid, as doses of 5mg can interfere with the efficacy of SP for IPTp.

Proposed USG activities: (\$1,260,000)

- 1. Procurement of SP: The year 1 goal of PMI is to achieve 50% coverage of pregnant women at risk of malaria with at least two doses of IPTp by procuring 840,000 doses (\$110,000). Commodities would be expected to arrive June 2008.
- 2. PMI will complement DfID- and WHO-supported training of 1,000 trainers and service providers in 17 districts in Nyanza and Western Provinces by extending that training to the community level in those same districts, in line with the MOH community strategy. The training will include 300 community workers in each district trained on FANC/MIP, including IEC/BCC sensitization and messaging for the recipient communities (\$90,000).
- 3. PMI will further expand training of trainers and service providers to the 29 additional malaria endemic districts (\$1,010,000). Both the trainings at the health facility level, as well as at the community level, are expected to begin in November of 2007
- 4. Training materials developed by the DRH and JHPIEGO will be printed and disseminated for the above trainings (\$50,000).

Insecticide Treated Nets (ITNs)

Current Status

The MOH National Malaria Strategy (2001-2010) includes the use of ITNs by at risk communities. The MOH, working with partners including NGOs, community based organizations (CBOs), faith based organizations (FBOs), the commercial sector and bilateral and multilateral organizations, promotes a whole market approach to distribute ITNs to biologically and economically vulnerable populations. The MOH with support from WHO and DfID is currently revising its strategic framework for ITNs.

Considerable progress has been made recently in increasing access to ITNs. The 2003 DHS reported 22% of households in Kenya to own any bed net, with only 6% owning an ITN, although household ownership was of both was higher in urban areas. The DOMC estimates that since 2002, approximately 10.8 million nets have been distributed through various mechanisms, although approximately 40% of these were conventional nets that require re-treatment; the DOMC estimates that one-quarter of these nets have been re-treated in the last 12 months. A population-based survey conducted by CDC in late 2006 in six provinces with a high burden of malaria indicated that 67% of households owned at least one net of any type, and 51% owned an ITN, either an LLIN or any net treated in the last 12 months. Approximately 52% of children under five had slept under an ITN the previous night in this survey. Only 4.4% (n=647) of pregnant women had slept under an ITN the previous night in the DHS survey. This number increased to 36% in the CDC survey(n=182).

The DOMC set a target of 60% coverage of vulnerable groups by 2006 and 80% coverage of these groups by 2007. Vulnerable groups are defined as children under five and pregnant women. People living with HIV/AIDS, the elderly, orphans and the poorest of the poor have

been identified as additional target groups. Currently, multiple delivery mechanisms are used including free/highly subsidized ITNs provided through ANC clinics, routine and campaign EPI services, child health action days, community-based initiatives and retail outlets. The MOH also supports strategies to promote demand creation to ensure the development of a sustainable ITN market. The MOH encourages coordination of the distribution of free and highly-subsidized ITNs to avoid undermining the commercial sector.

23

The primary partner in the distribution of ITNs is Population Services International (PSI)² who have developed multiple distribution mechanisms. Prior to 2001, there were very few nets in Kenya with approximately 200,000 produced annually by local manufacturers. PSI initiated a pilot project selling the branded "SupaNet[®]" in Coast Province in 2001. The program was expanded the following year with targeted subsidies for rural communities. Conical nets were sold in urban areas at 320 Ksh (\$4.80) each and rectangular nets were sold in rural areas at 200 Ksh (\$3.00) each. Re-treatment kits were available at clinics for 30 KSH. By 2004, it was clear that price was still a major barrier to uptake of ITNs in the rural areas and the price for a rural trade net sold in shops and kiosks was reduced to 100 KSH (\$1.50). PSI further subsidized the nets by providing a free treatment kit bundled with the nets. PSI also introduced highly-subsidized LLINs which were sold at antenatal clinics for 50 KSH (\$0.75) for pregnant women and children under five. The LLINs sold through the clinics included both PermaNets[®] and Olyset[®] nets. By the end of 2006, PSI had sold more than nine million nets. During 2006, more than 500,000 nets were sold through the commercial sector. Net sales at clinics in 2006 averaged almost 200,000 per month.

In 2006, with GFATM support 3.4 million free LLINs were distributed to children under five in conjunction with a measles vaccination campaign. A post-campaign evaluation showed that household ownership of an ITN rose from 40% to 51%, the proportion of children under five sleeping under a net rose from 35% to 52% and the number of pregnant women who slept under a net rose from 25% to 36%.

Approximately 40% of nets currently in use are non-LLINs. Re-treatment kits are available at 20 Ksh each (\$0.30) at clinics, although utilization of these services is limited. With support from DfID, WHO has funding to purchase re-treatment kits for the approximately three million untreated nets currently in circulation. PSI is beginning to bundle the KO-Tab 123 with locally manufactured nets that are sold through the rural sales outlets. These nets will likely need re-treatment, but it is unclear how this will be accomplished.

The DOMC estimates between 3-5 million nets per year will be needed over the next few years, including distribution through ANC clinics, replacement ITNs, and ITNs for the economically vulnerable and other vulnerable groups. Currently 1 million nets per year are provided through the GFATM grant; and approximately 1.4 million provided by DFID and distributed by PSI through the ANC clinic program, leaving a gap between 500,000 and 2.5 million, the higher range (2.5 million nets) covering not only PMI's target groups, but replacement nets, PLWHA, orphans, and the poorest as well. PEPFAR is planning to provide two nets with each care package to people testing positive for HIV/AIDS.

² Supported primarily through a grant from the Department for International Development. This program has also received some support from USAID.

An IEC program to raise awareness of malaria and its prevention is funded by DFID. The program involves radio, television, road shows and theater. Based on a PSI evaluation, awareness that ITNs are one of the most effective malaria control measures rose from 3% in 2000 to 74% in 2005. Further IEC/BCC is necessary particularly at the community level to ensure that ITNs are used every night as evidenced by findings from CDC's post-campaign survey, where 22% of nets owned by households were not hanging/used at the time of the survey. The DOMC is in favor of examining the barriers to ITN use while developing IEC/BCC strategies to address these issues and increase use.

DfID will support the NMCP with 9.5 million sterling pounds over the next year, although their continued support for the clinic distribution and social marketing program has not yet been confirmed and is contingent on the finalization and adoption of the national ITN implementation framework, currently under development. Based on drafts of this framework, it is likely that Kenya will move to a system of free distribution of ITNs, ultimately using KEMSA as the means of distribution. If that approach is adopted, a careful transition plan will have to be developed, with continued support to the ANC and EPI clinic program in the interim. Currently, KEMSA is not responsible for the procurement and distribution of ITNs, and the capacity to do that would have to be developed.

During the PMI stakeholder's meeting, high priority was placed on the need to use multiple channels to distribute ITNs including clinics, periodic/targeted campaigns, the private sector and other platforms, including workplace programs and military facilities. The discrepancy between ITN ownership and use of nets was identified as a major concern and a recommendation was made to conduct some targeted operations research to better understand the reasons for not using ITNs and to use community groups to a far greater extent to increase the appropriate use of ITNs already in households.

Proposed USG Activities: (\$5,890,000)

- 1. Help fill the ITN gap by purchasing 600,000 additional LLINs to distribute through the ANC clinic program and provide support for this program, particularly as Kenya transitions to a new ITN framework strategy. (\$4,600,000)
- 2. In line with the MOH community strategy, engage CBOs, FBOs, and other NGOs in a stepped up targeted program at the community level to increase the appropriate use of ITNs by vulnerable groups through IEC/BCC activities providing communities with information on why ITNs should be used, and how to use them. (\$915,000)
- 3. In collaboration with the DOMC, WHO and DfID, purchase LLINs for replacement of torn or damaged conventional nets as part of a retreatment/replacement campaign supported by DfID/WHO (\$375,000)

Indoor residual spraying (IRS)

Current Status/Challenges and Needs

Indoor residual spraying is currently done in parts of 16 epidemic-prone/seasonal transmission highland districts in western Kenya. The total population in these areas is approximately 6.5 million; of these, in 2006, approximately 200,000 households with a population of about one million were targeted for IRS. However, the spraying was coordinated at the district level where there was little capacity to properly plan, manage and evaluate the IRS activities. With GFATM funding from Round 4, the DOMC is taking a lead on coordinating IRS in these 16 districts. A WHO technical advisor assisted with planning of the IRS campaign at the national level in January 2007. Training of trainers was initiated mid-February 2007 and spraying began in mid-April 2007. An estimated 680,000 households are targeted for spraying in 2007 with one million households targeted for 2008.

However, there are still several gaps that remain for the current spray cycle. While \$3.8 million from the GFATM has been allocated for IRS for 2007, there is an estimated shortfall of \$2.3 million. USAID-Kenya has money that has been earmarked for IRS but this is unlikely to cover the shortfall. The DOMC has revised its targeted number of households to 340,000 throughout the 16 districts. Therefore, the district health management team (DHMT) in each district identified "hot spots" based on the number of malaria cases where IRS would be targeted in 2007. A stakeholder's meeting before the start of the campaign identified several logistical problems, including a shortage of insecticide and equipment, lack of transport and storage problems for insecticide and equipment that have been procured, and inadequate IEC. A recommendation was made for technical assistance to help with the planning and organization of the 2008 IRS campaign.

With rapidly increasing coverage of ITNs throughout Kenya, there have been anecdotal reports of greatly reduced malaria incidence throughout the country, including the highlands. Two questions that need to be addressed are whether IRS is a cost-effective strategy in epidemic-prone areas as the overall case burden is going down, and how to best combine the use of IRS and ITNs in a comprehensive vector control strategy. A third question is whether to implement the IRS strategy in neighboring endemic areas. These decisions will require enhanced surveillance and monitoring in sprayed areas to assist the DOMC in making decisions about where to allocate resources for IRS. The DOMC is planning to conduct parasitological and entomological evaluations of the IRS program, but this evaluation needs to be strengthened and expanded. With the high ITN coverage and reports of reduced malaria burden at health clinics, it may be possible to provide more targeted coverage of IRS in these highland districts.

To help answer the second question, an evaluation of integrated vector control in high and low transmission areas of western Kenya. The study will evaluate:

- (1) Effectiveness of combining IRS with ITN use compared to ITNs alone in areas of high and low transmission.
- (2) ITN use/adherence in areas covered by IRS.

The Kenya MOP calls for IRS to be implemented with full coverage in two highland districts and two neighboring lowland districts. The study will take place in these four districts, along with two additional highland and lowland districts. The two additional highland districts will have

limited IRS, with about 10% coverage, and the two lowland districts will have no IRS. All are expected to have similar levels of ITN ownership. To evaluate the combined effectiveness of the two interventions we will measure prevalence of parasitemia and anemia in children aged 6 months to 15 years. This will be done by conducting cluster randomized cross-sectional surveys in 1500 households across 8 districts. The survey will be conducted within six weeks of the end of the rainy season, most probably May-July 2008.

Three insecticides are approved for use in IRS in Kenya: lambdacyhalothrin (ICON®), deltamethrin (K-Othrine®), bifenthrin (Bistar®). All three are pyrethroid insecticides, the same class of insecticides recommended for use on ITNs. Pyrethroid resistance has previously been detected in western Kenya in the context of a small study of pyrethroid treated nets and curtains. As ITN coverage has expanded, there is evidence of increasing frequencies of the kdr allele—a marker of insecticide resistance—in natural mosquito populations. Given these findings, it was recommended that Kenya consider the use of non-pyrethroid insecticides for IRS as part of an insecticide resistance management strategy. At the stakeholders' meeting, small-scale testing of non-pyrethroids was proposed to determine their duration of efficacy on a variety of surfaces before incorporating them into the national malaria control strategy.

Proposed USG Activities: (\$4,075,000)

- 1. Provide technical assistance to the DOMC to refine their IRS strategy for epidemic prone areas in the highlands of western Kenya and assist with planning for the 2008 IRS campaign. This support will include additional training for spraymen and supervisors, development of a comprehensive IEC program to sensitize communities to the IRS campaign and assistance in planning and managing the logistics of the IRS campaign. (\$250,000)
- 2. Support IRS in two highland and in two neighboring endemic districts targeting 85% coverage in all four districts.(\$3,500,000) (Note, if the endemic districts require two rounds of spraying during the year 1 time frame, PMI would implement IRS in only three districts, including 2 rounds in one endemic district).
- 3. Provide support for enhanced surveillance and monitoring in the four districts to document the effectiveness and cost-effectiveness of IRS in both endemic and epidemic-prone areas. (\$175,000)
- 4. Monitoring insecticide resistance The widespread use of synthetic pyrethroid insecticides is a key component of malaria transmission reduction, in accordance with the national policy. These insecticides will be used as the active ingredient on ITNs and for IRS. As such, it is critical that monitoring for insecticide resistance among the vector population be supported. PMI will support the monitoring of insecticide resistance in 10 sentinel sites. (\$100,000)
- 5. Evaluate the effective half-lives of non-pyrethroid insecticides on traditional house wall surfaces. If the effective lifetime of these non-pyrethroids is similar to that of the insecticides currently used for IRS, they should be considered for incorporation into the IRS program as an insecticide resistance management strategy. (\$50,000)
- 6. Evaluation of integrated vector control with both IRS and ITNs in high and low transmission areas of western Kenya (core funds).

Case Management

Pharmaceutical Management and Treatment

Current Status and Needs

The documented emergence and spread of *P. falciparum* resistance to Kenya's first-line treatment, SP, and second-line treatment, amodiaquine, led to a change in malaria treatment policy to AL as the first-line treatment for malaria. Kenya is in the early phases of rolling out its new malaria treatment policy which was approved in April 2005 and officially launched on September 2006.

Treatment Policy

Second-line treatment for uncomplicated malaria is oral quinine. Parenteral quinine is also recommended for treatment of severe malaria. In the absence of quinine, injectable artemether, injectable artesunate, or artesunate suppositories are recommended for pre-referral care at the health centre or facility level. At present, only limited quantities of any drug other than quinine are available.

Procurement and Quantification

The DOMC quantified the requirements for AL over a five-year period in December 2003 using an epidemiological model that estimated morbidity using data from health management information system and data from government hospitals, health centers and dispensaries. The quantification included both the public health system and the Mission/NGO sector. Currently, 30% of treatments are allocated to the Mission/NGO sector. KEMSA, the public sector medical stores and supply system, manages the distribution and logistics of the AL for the public sector. MEDS manages drugs and essential health commodities for the Mission/NGO sector, which accounts for 30-40% of health facilities. The quantification for severe malaria drugs and second-line treatment was based on an estimate that assumes that 5% of malaria cases will develop severe malaria or require second-line treatment.

The DOMC received funding from the GFATM Round 4 grant (2006-2011) for the procurement of AL and severe malaria drugs based on these quantifications. Deliveries of AL began arriving in 2006 and 12 million treatments have been procured to date.

It appears that the initial quantification for AL and severe malaria drugs for both the public and NGO/mission sector was underestimated and there will likely be a supply gap through the end of 2008. Several facilities are reporting stockouts at the present time. There are several possible reasons and contributing factors. First, the supply chain management system operated by KEMSA is strained and distribution remains a major challenge. Second, several new health facilities are being built under the Community Development Fund initiative. Although it is unclear when these facilities will be operational, KEMSA expects to supply an additional 566 health facilities which were not originally planned for. Third, only 46% of the Mission/NGO

facilities are currently ordering AL. This is most likely due to the fact that the ACT training has not caught up to all the facilities and that the demand for AL is likely to go up once all facilities have been trained and oriented on the new policy. Finally, over-diagnosis of malaria is most likely occurring with the introduction of a new, efficacious antimalarial and weaknesses in diagnostic capacity. With only 16% of health facilities currently reporting consumption data, it is difficult to quantify the exact gap. However, there is consensus that a gap exists. A comprehensive quantification exercise is planned later this summer by the DOMC, KEMSA, and rational pharmaceutical management plus (RPM+), which will provide additional information on anticipated gaps.

Currently, the DOMC is estimating a gap for severe malaria (using age-based population, weight categories, expected proportion of severe episodes--5% of all malaria cases, and expected number of episodes for year) of approximately \$3,000,000 USD after the GFATM contribution to cover all drugs including quinine and injectable artemether and artesunate, and ancillary supplies such as needles and syringes.

Case Management Training

In 2006, the DOMC with partner support rolled out training on the new treatment guidelines to public, NGO, and selected private sector health workers at all facility levels. The three-day training was carried out through a cascade training approach using training of trainers. It is clear that not all health workers in the public or Mission/NGO sector were reached. There appears to be an acute gap in training for the Mission/NGO sector. Data from MEDS reveals that a significant portion of the NGO/Mission recipients eligible to receive and distribute AL are not doing so and are still adhering to the previous guidelines. The DOMC estimates that only half of the health workers in all sectors have been trained to date and case management in accordance with the new guidelines remains weak. Training that PMI will support in Year 1 is meant as a vertical catch-up activity for facilities not yet trained in case management of malaria. Supervision of health workers in malaria case management will be the responsibility of the DHMT, and include clinical officers at health facilities. An evaluation of health worker performance in case management will be conducted in 2009 as part of the SPA.

In addition to the training of existing health workers, there is a need to incorporate the new guidelines into the pre-service curriculum at all the major universities and health worker training facilities to ensure that new health workers are fully trained. Pre-service curriculum development is a major gap that needs to be filled.

The need to integrate comprehensive malaria case management into the IMCI strategy and rollout is also recognized as a need. However, ensuring that all health workers are caught up and updated on the treatment guidelines is viewed as the most urgent priority. There is also discussion and interest at examining community based strategies for ACT distribution. However, consensus exists that a pharmocovigilance system needs to be in place prior to introducing ACTs through community health workers. Both of these approaches are longer-term strategies that may be supported in future years.

Drug Management and Supply Chain

The procurement of all the GFATM financed AL is currently being managed by KEMSA, through the GFATM Procurement Consortium (comprised of KEMSA, JSI, Crown Agents, the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ)), and MEDS. KEMSA provides procurement, distribution, logistics and storage for antimalarial medicines for all public sector health facilities in Kenya. MEDS provides this service for the Mission/NGO sector.

The distribution of antimalarial medicines, including ACTs, to the public health sector is integrated into the government and mission-sector distribution systems. KEMSA and MEDS handle the quantification and procurement of other antimalarial medicines and commodities required to implement the malaria treatment policy in public and mission facilities through existing procurement mechanisms financed through the GOK budget and mission-sector facility funding. KEMSA is an independent entity that receives minimal funding from the GOK, but receives funding from donors and through fees levied on warehousing and distribution. KEMSA distributes malaria medicines and commodities to primarily through a "push" system (except for public hospitals). MEDS is also primarily donor funded and sustains its operations through a revolving drug fund. MEDS primarily operates on "pull" system, based on demand from its health facilities. KEMSA was also recently awarded a threshold grant from the Millennium Challenge Account (MCA) for strengthening KEMSA's procurement capacity and accountability.

The ACT rollout has added an additional burden to the already stressed supply chain systems, particularly KEMSA. The procurements of AL are outside of KEMSA's annual procurement cycle, which adds another step to an already difficult process. AL deliveries are held within KEMSA central warehouse and the allotted quantities (30%) are then picked up by MEDS for the Mission/NGO sector. Distribution, particularly through KEMSA, has been challenging leading to stockouts at the facility level. Inadequate storage at all levels of the supply chain (central, district, and health facility) has been identified as a key concern as well. Funding and capacity for operations and distribution have been inadequate.

The Pharmacy Division of the MOH implements pharmaceutical inventory management activities in public health facilities. In preparation for the deployment of AL, health workers from 1,211 health facilities in both sectors received inventory management training focused on ensuring AL stock availability, minimizing wastage and reducing leakage of stock, and collecting consumption data for future reordering and redistribution of AL stock. Bin cards and registers were distributed with AL consignments and are supposed to be used to record stock movements. The flow of data is inadequate and the data recovery rate is low. There is a need to computerize inventory management all the way to the district level to monitor stock, consumption, and orders.

Drug Regulatory Status, Pharmacovigilance

The Pharmacy and Poisons Board (PPB), an arm of the Ministry of Health, is the Drug Regulatory Authority in Kenya. PPB is responsible for regulating the pharmacy practices and the manufacture and registration of pharmaceuticals. AL is currently scheduled by the PPB as a prescription-only medicine. This status precludes the provision of AL through community based

or private sector approaches that require over-the-counter status. There is consensus in-country that a pharmacovigilance system for AL needs to be established before AL can be made available over the counter--which is a priority. There is other donor funding in place to assist with the development of the pharmacovigilance system. In addition, Novartis is contributing funds to establish a pharmacovigilance system in the private sector. Until this system is established, and the regulatory status changes, limited opportunities exist to expand access through the private sector or community health workers.

Proposed USG Activities: (\$5,580,000)

In Year 1, the PMI will focus on strengthening the implementation of the ACT rollout through support for strengthening diagnostics, pharmaceutical management, continued focus on health work training for case management, and commodity gaps. Several implementation challenges have been identified over the past six months as the ACT rollout has moved forward. PMI will complement resources already available through the GFATM and DfID to fill in gaps and achieve targets. Specifically, the PMI will support the following:

- Procure 2.5 million treatments of AL and severe malaria drugs to fill in supply gaps in the public and Mission/NGO sector. (\$4,300,000)
- Health worker training on new treatment policy guidelines--The DOMC estimates that only half of all health workers (public, mission/NGO, private) country have been trained on the new treatment guidelines. PMI will support the three-day training of an additional 3,200 health workers throughout endemic districts in the country, particularly focusing on mission/NGO sector health workers that were not reached during the initial training efforts. (\$640,000)
- Support for pre-service curriculum development for all level of health professional that incorporates the new malaria treatment guidelines. This activity will facilitate the cooperation of DOMC, Kenyan Universities, and training institutes to ensure that all health professionals receive comprehensive training on malaria case management, including incorporation into IMCI guidelines, and treatment of severe malaria. JHPIEGO will coordinate this development, with TA as needed from other organizations. (\$100,000)
- Strengthen drug management, supply chain logistics and inventory management of AL through the public and NGO/mission sectors. This activity will primarily provide technical assistance to KEMSA in several key areas including distribution, quantification, and an MIS reporting system aimed at strengthening inventory management at the District level. In addition, collaboration and support to MEDS when required will be another focus of this activity. (\$540,000)

Malaria Diagnosis

Current Status, Challenges, and Needs

National Guidelines for Diagnosis, Treatment, and Prevention of Malaria in Kenya (MOH, 2006) describe the role of diagnosis in the management of uncomplicated malaria as follows:

- For children under five years old:
 - o In high malaria endemic areas, any child with a fever or history of fever should be presumptively classified and treated as malaria. The use of parasitological diagnosis is not a prerequisite for treatment.
 - o In low malaria endemic areas, any child with fever or a history of fever in the absence of measles, running nose, or any other identifiable cause of fever should be presumptively classified and treated as having malaria. The use of parasitological diagnosis is recommended where possible. (underline added by authors)
- Children ≥ five years of age and adults
 - o In all patients with fever or a history of fever the use of parasitological diagnosis is **recommended**
 - At health facilities where malaria diagnostics (microscopy or RDT) are not available, patients with a fever or history of fever in whom the health worker strongly suspects malaria and has eliminated other possible cause of fever should be presumptively treated as malaria

Presently, there is no national policy outlining the goals, standards, and strategies for diagnosis of malaria in Kenya, although a general document outlining resource needs for strengthening the national laboratory system is under development. The DOMC has indicated that strengthening of malaria diagnosis through improved microscopy would be desirable, and there is also considerable interest in exploring how RDTs could be used at health facilities to improve treatment decisions. It is unknown what percent of malaria cases in Kenya are parasitologically confirmed.

Interviews with DOMC staff have suggested that all provincial and district hospitals had microscopes and laboratory technicians capable of performing malaria diagnosis. However, old, malfunctioning, or missing microscopes need to be replaced at these facilities. Moreover, since the same microscopes are used for bacteriology, tuberculosis smears, and stool parasite examinations, additional microscopes could enhance capacity for efficient malaria diagnosis. Global Fund monies have not been earmarked for purchase of microscopes. PEPFAR and other partners recently purchased some microscopes, primarily to support tuberculosis diagnosis.

DOMC staff indicated that based on a health facility survey conducted in four representative endemic districts several years ago, ~60 % of health facilities below the district hospital level did not have capacity to perform microscopic diagnosis of malaria, though how much of this was due to lack of microscopes, lack of trained personnel, lack of supplies or any combination thereof is not known.

There is a general acknowledgement that there are an insufficient number of trained microscopists to adequately staff larger health centers and dispensaries. Equally pressing is the need to re-train many of the existing laboratory technicians at district and provincial level to improve the quality of malaria diagnosis. In Year 1, PMI will focus on training for malaria microscopy, exploring ways to integrate training with PEPFAR and the national TB program in Years 2 and 3. Walter Reed is currently conducting laboratory training for PEPFAR, and will

conduct trainings for field microscopists for PMI in Year 1. WR will evaluate laboratory worker performance post-training.

Supervision of microscopists is lacking. The National Public Health Laboratory (NPHL) oversees lab work at the provincial level, which then is supposed to oversee the district level, but the NPHL is currently in a capacity building phase with limited supervisory capacity. District level supportive supervision of microscopists is better, but still hindered by the usual impediments such as lack of funds, vehicles, petrol, and other competing demands on time.

At the present time, RDTs are not widely used in Kenya, though current treatment policy proposes their use for parasitological diagnosis where microscopy is not available. DOMC has gained limited experience with RDTs (ICT Parasight F^{\oplus}) at the Health Dispensary level in highland areas as part a plan to quickly detect and manage malaria epidemics. A recent research study by KEMRI/CDC and KEMRI/Wellcome Trust has shown high (~90%) sensitivity and specificity of RDTs when used by trained health workers at peripheral facilities, but poor acceptance of RDT results by these same health workers to guide treatment decisions. DOMC expressed substantial interest in obtaining additional information on how best to use RDTs and improve their acceptance before rolling them out nationwide.

For PMI, malaria laboratory diagnosis is a key component of good case management. In Kenya we noted several important gaps in malaria diagnosis. An overall malaria laboratory policy and strategy is needed to guide how malaria diagnosis (both microscopy and RDTs) will be performed at different levels of the health system. A laboratory needs assessment should be performed to guide future equipment, training, and human resource decisions. Improvement of microscopy capacity at Provincial and District levels including equipment purchase and technician re-training is needed. With the new first line antimalarial (artemether-lumefantrine) costing considerably more than SP, the DOMC would like to move to RDT use at peripheral facilities to decrease the unnecessary use of antimalarials that occurs when patients are presumptively treated. However, there is a need for a pilot implementation of RDTs at District level to gain additional experience with them at a smaller scale before rolling out nationwide.

Proposed USG Activities: (\$620,000)

- 1. DOMC and WHO/DfID, with technical support as needed from PMI and other partners, will develop a national laboratory policy and strategy for the use of microscopy and RDTs at different levels of the health system and in different epidemiologic settings (funded by DfID, no cost to PMI).
- 2. In collaboration with the DOMC and other partners, perform a national laboratory needs assessment to more accurately define gaps in human resources, training, equipment and supplies to guide future resource allocation. (\$100,000)
- 3. Provide on-the-job training for 80 laboratory technicians (one from each district and province) on malaria smear preparation, staining and microscopic diagnosis (\$120,000)
- 4. Procure microscopes. Eighty binocular microscopes will be procured for each District and Provincial laboratory. (\$200,000)
- 5. RDT pilot evaluation. In two Districts, RDTs will be rolled out to all peripheral health facilities without microscopy after training of health workers on their use. A quality assurance system will be established in each district to collect smears on a random

sample of RDT negative and positive patients, read them at the District laboratory, and feed back RDT performance results to health workers. Health worker treatment decisions and concordance with RDT results will be recorded, and a behavioral scientist will conduct in-depth interviews with a sample of health workers using RDTs reasons to assess reasons for adherence or non-adherence to RDT results. This pilot will provide practical experience on RDT at District level before a potential nationwide rollout. (\$200,000 country, and \$200,000 core)

EPIDEMIC PREPAREDNESS AND RESPONSE

In Kenya, 16 districts are known to have seasonal transmissions that are epidemic prone: three in Nyanza Province; 11 in Rift Valley Province; and two in Western Province. In addition, four other districts in the North Eastern Province experience epidemics, usually associated with heavy rains and flooding. The total population of these districts is 6,559,437 million. Previously, Kenya relied mainly on case management for the control of epidemics, but began implementing preventive measures in 1998 with the help of various partners.

Indoor residual spraying in the epidemic-prone areas was started in 2006. Problems encountered included a limited capacity at the district level to plan, manage, and evaluate, as well as funding gaps for transportation and storage. As a result, it was recommended that IRS capacity in all the epidemic districts be developed as part of the malaria epidemics preparedness plan. Additionally, mapping was suggested to target the spraying.

Malaria Early warning system (MEWS)

The development of a Malaria Early Warning Systems (MEWS) was started in Kenya in 1999 as part of the Highland Malaria Project, and was successfully piloted in two of the districts with seasonal transmission. As part of this project, five representative sentinel surveillance sites were selected in each of the two districts to gather high quality prospective data for use as an early warning for a potential malaria epidemic, and early detection of an ongoing epidemic. The sites are health institutions in each district (hospitals, health centers and dispensaries) that report weekly on malaria morbidity and mortality, laboratory confirmed cases, and meteorological indicators. In each site, epidemic thresholds using retrospective data from the last five years have been defined to assist in the early detection of malaria upsurges.

This sentinel surveillance system is now planned for expansion in the other 14 epidemic-prone districts. To this end, the districts were urged to identify possible sentinel sites that could be used and start collecting the five year retrospective data that will be used for generating the epidemic threshold curves. It is expected that with technical support from the HIMAL project, a workshop will be convened to train all the new districts on epidemic thresholds and its use in monitoring for increases in the number of cases of malaria. There is a gap in financing for this activity and for the data collectors that assist in data management at each of the sites.

The information used by the health services as part of MEWS is also collected by other government sectors (e.g. rainfall data by the meteorological services and population movement data by the national statistics department). A successful MEWS thus depends on effective inter-

sectoral collaboration, and indeed there has been collaboration with the meteorological department for rainfall and temperature data. Further collaboration needs to be promoted from which the DOMC can obtain critical MEWS information in order to develop appropriate and sustainable early warning systems. This could include possible financing of additional parameters from the meteorological department estimated at about \$2,000 per parameter per year, which may assist in the development of tools that will help Kenya to anticipate and plan for anomalies in climate such as drought, floods and violent storms to predict potential increases in malaria incidence or epidemics.

To support the MEWS, mapping is planned to provide each of the districts more accurate geographical data to be used for IRS implementation plans. There is a currently a company being contracted to assist with the mapping. After the relevant data is collected, maps will be generated to assist with planning.

Malaria epidemic response

DOMC currently works with the provincial and district outbreak management teams in preparing and responding to malaria epidemics. At each of these levels there is an epidemic preparedness plan that can be used to guide the response. District capacity to adequately detect, prepare and respond to confirmed epidemics is still limited. With support from the GFATM Round 2, supplies that will be used for IRS as part of preparedness plan for malaria epidemics for the 16 districts over the next two years have been procured. However, there is shortage of storage space for all these equipment and insecticides. Also, since the whole area to be sprayed is not yet mapped out, the procured supplies may be inadequate.

Proposed USG activities: (No additional cost to PMI)

- 1. Technical assistance and support for implementation and management of IRS in two epidemic-prone districts, including TA on environmental assessments and alternatives to pyrethroid use (see IRS section).
- 2. Support for surveillance through WHO and CDC in the two epidemic-prone districts where IRS will be supported (see IRS section).
- 3. Nationwide support of the health management information system (HMIS) system to improve reporting from districts to the central level, as well as supervision and the roll-out of HMIS registers (see M&E section).

SURVEILLANCE, MONITORING & EVALUATION

HMIS

The Kenyan HMIS has not been functioning well, resulting in a lack of reporting from many districts and a lack of data at the national level to support planning for specific programs. Most health facilities report monthly to the districts, although this information is not transmitted to

provincial and national levels resulting in only about 1% of health information reported at the national level. There are also no indications as to how this data is used at the various levels of the health system. Problems identified have included: too many indicators; lack of standardized registers and tools; multiple vertical surveillance systems; computer-based systems used for data entry causing work overload for the lower-level health workers; and no clear cut reporting channels. This was further hampered by programs advocating for additional indicators as they expanded the scope of their work. As part of the health sector reforms taking place in Kenya, the importance of the role of HMIS in monitoring progress was identified, resulting in a change in management.

In support of these changes, the MOH relegated responsibility for data collection and coordination solely to the HMIS unit. Individual departments in the MOH agreed to come up with harmonized registers and reporting formats. As part of this, all programs identified the key indicators that could be monitored under HMIS, which were then discussed and included if appropriate in the registers and tools. For the case of malaria control, five indicators were identified for inclusion:

- number of nets distributed to pregnant women and children under five years;
- proportion of pregnant women receiving IPTp 1 and 2;
- number of households sprayed;
- case fatality rate due to malaria; and
- stock-outs of tracer drugs AL in the case of malaria.

One of the activities undertaken with the MOH's changes was the selection and reduction in number of indicators. The number was reduced from about 46 to 27 in line with the "Kwale" model. The "Kwale" model that is currently being scaled-up was a pilot funded by the Aga Khan Foundation that successfully demonstrated that information if limited to a minimum can be used for planning purposes. In this model, only 27 indicators from the different health programs are monitored and appropriate databases established at district level to support planning purposes. This is the model that is currently being rolled out in districts, and was initially done so in North East that has been implementing for one year, Nyanza that has been implementing for six months and Coast province. It is funded by DANIDA, and is expected to be scaled-up to all districts in the next five years. The estimated cost over the five-year period is approximately \$78 million. This, however, has only been established up to the district level, and the provincial and national packages are currently being developed and will be implemented in the course of this year.

Malaria Information and Application System (MIAS)

Due to the more stringent requirements of the DOMC to monitor progress and report to various partners such as the GFATM, a Monitoring and Evaluation unit was established. Funding for M&E is currently being supported through USAID and RPM Plus technical assistance. An assessment of the status of data sources for malaria information and data availability to the DOMC was done in early 2006. The assessment highlighted the need for: 1) agreement on a minimum set of indicators for overall malaria monitoring; 2) strengthening the data sources for routine monitoring of performance-based financing results, survey data, training data, etc. for the various malaria interventions; 3) establishment of a networked database on the DOMC server; 4)

capacity building of DOMC staff in the use of the MIAS system; and 5) support to departments and districts aimed at strengthening data flow. The M&E working group of the DOMC has been working to support activities under the M&E unit, and developed the minimum set of indicators required for reporting on malaria program progress. Data sources currently targeted for strengthening and accompanying activities include the following:

- HMIS for routine malaria monitoring support harmonization of HMIS registers, support strengthening HMIS data flow process;
- Other divisions including DRH, Division of Child Health (DCH), etc.- support capacity building for the collection and sharing with the DOMC of relevant data;
- Planning and coordination of surveys within all intervention areas establishment of a survey database with tools, data and reports of completed surveys and timelines for planned surveys;
- Performance-based monitoring information from GFATM grant implementers currently being piloted in four districts with the intention of scaling-up if this is successful.

Population-based Surveys

The last DHS in Kenya was in 2003, and one is planned in the early part of 2008. The 2003 survey demonstrated low coverage of treatment and prevention measures, and led to efforts to increase financing of these interventions, including increasing ownership and use of ITNs through a number of different service delivery mechanisms. A Malaria Indicator Survey (MIS) was conducted in June and July 2007, funded primarily by DfID and WHO.

Facility Surveys

A facility survey organized by the MOH's Division of Child Health IMCI program was completed last year in which health worker practices at different levels of health care were assessed. This demonstrated low performance on most childhood indicators. There are no plans to carry out another one in the near future although it may be considered in 2009 as part of the Kenya Service Provisions Assessment (KSPA) planned by USAID.

Demographic Surveillance System (DSS)

A DSS site was established for continuous demographic monitoring of a geographically-defined population (135,000) and have been monitored since 2001 as a collaborative effort between CDC and KEMRI. A similar site was set up in Kilifi by the Wellcome Trust and KEMRI collaboration. These sites monitor: birth rates; mortality and morbidity rates; socioeconomic indicators; and conduct verbal autopsies to ascribe probable causes of all deaths. In addition, all known pregnancies and pregnancy outcomes are recorded, and the site in Kisumu also collects EIR data (ongoing since 1990).

As part of the DSS in Kisumu, there is a health facility component. At each health facility, fevers are assessed and proper treatment given. Every child admitted has a routine blood smear done and questionnaire filled out and all diagnoses and treatments are recorded. Data has been

collected on community parasitemia and anemia prevalence in 2003, again in 2006, and now annually to measure impact of DOMC interventions, such as introduction of AL.

Sentinel Sites

The Wellcome Trust and KEMRI have established sentinel sites, which have focused assemblies from 1999 through to March 2007 looking at month-by-month pediatric (0-15 years) admissions by malaria versus non-malaria diagnosis in seven hospitals. Quarterly data is gathered from inpatient registers and death certificates, as well as information on climate, ITN sales and figures, and drug supply. Additional parameters could be added to gather data relevant to PMI.

Proposed USG Activities: (\$910,000)

- 1. Assist the MOH in a nationwide roll out of the new HMIS data collection As the MOH has now harmonized the various separate registers that were previously used for HMIS, and incorporated key questions to improve the ability of the HMIS to report on key malaria indicators, PMI will assist with the roll out of the registers and data collection tools. (\$50,000)
- 2. Support established DOMC/Wellcome Trust/KEMRI sentinel sites to collect both inpatient and outpatient malaria morbidity and mortality data (\$200,000)
- 3. DHS population-based survey, malaria component The DHS will provide estimates of malaria outcome and baseline impact indicators, all-cause mortality and malaria-specific mortality for children age less than five years. Verbal autopsies will be conducted for all deaths to children who died at ages less than five years to ascribe causes of death, including malaria. (\$300,000)
- 4. Facilitate reporting and supervision for HMIS The HMIS will be a continual source for collecting data for key malaria indicators. As this revamped system is rolled out, it is important that appropriate supervision be supported to ensure proper data collection and reporting. PMI will support these supervisory visits to ensure quality data collection and reporting. (250,000)
- 5. Investigation of causes of deaths from health facilities relative to DSS The DSS routinely conduct verbal autopsies on all deaths reported through routine community surveillance. There is a interest within PMI to better understand how causes of death for deaths at health facilities compare to those in the community to consider the potential for tracking malaria mortality through health facility data. Methods will be established to collect verbal autopsy data on facility deaths and make appropriate comparisons with deaths routinely reported to the DSS. (\$75,000)
- 6. Monitoring and evaluation system strengthening tool (MESST): stakeholders meeting utilizing the RBM tool to develop an M&E strategy with the DOMC (\$35,000)

HIV/AIDS and MALARIA

Kenya is a PEPFAR focus country, and has a severe generalized epidemic with estimated adult HIV prevalence of 6.1% (UNAIDS, 2006) which translates into 1.2 million HIV-positive Kenyans over age 15 and approximately 150,000 infected children under 15. An estimated 140,000 Kenyans died of AIDS in 2005. Deaths to date have left 1.1 million children orphaned by AIDS. The Kenyan epidemic varies significantly from region to region, with Nyanza

Province affected by prevalence rates approximating those in some Southern African nations. Women are nearly twice as likely as men to be infected.

The USG is the predominant supporter of HIV/AIDS interventions in Kenya, with FY 2007 funding of over \$300 million. DfID is the next largest bilateral donor, and other HIV/AIDS donors include the Japanese International Cooperation Agency, Germany's GTZ, and the World Bank. In addition, the GFATM has approved HIV grants totaling nearly \$130 million.

In Kenya, PEPFAR supports a comprehensive package of services including basic prevention and treatment programs. PEPFAR has made investments in laboratory capacity building, including training of laboratory technicians and purchase of expanded stocks of test kits. In addition, PEPFAR is implementing the Uganda basic care package in Nyanza province, which includes ITNs. In future years, the basic care package will be rolled out in other high prevalence provinces.

There are several opportunities for interaction and synergy between the PEPFAR and PMI programs in Kenya. Nyanza Province has the highest rates of HIV prevalence, and is also one of the provinces with the highest rates of malaria transmission. Specific areas of potential collaboration include:

Proposed USG Activities: (No additional funding-covered under other sections)

- 1. ITNs in Nyanza Province: PEPFAR will be distributing ITNs to people living with HIV/AIDS as part of its basic care package in Nyanza Province. Increasing access to and use of ITNs in Nyanza and other malaria endemic provinces is also a priority for the PMI program. PEPFAR and PMI can share information on ITN distribution, and data from the PMI-planned operations research study on barriers to use of ITNs will also be shared with PEPFAR. Another ITN-related activity for the PMI in year 1 is to work with community-based organizations and NGOs to improve the appropriate use of ITNs by vulnerable groups. It is likely that there will be opportunities to interact with community based organizations working under the PEPFAR program.
- 2. Laboratory strengthening: PMI will build on the laboratory training system and approach used by PEPFAR through Walter Reed Army Institute of Research. PMI will also collaborate closely with PEPFAR to ensure PMI's laboratory investments are complementary to those of PEPFAR, as much as possible.
- 3. Coordination at provincial and district levels: PMI's support for further scale up of the malaria in pregnancy training at the facility and community levels will be undertaken by the USAID-managed APHIA network. HIV/AIDS activities including work with ANC centers for prevention of mother to child transmission make up a significant portion of the APHIA program. With APHIA providing support to district-level facilities and to the district health management teams on both HIV/AIDS and malaria interventions, there are tremendous opportunities for synergy and coordination.

CAPACITY BUILDING WITHIN THE NATIONAL MALARIA CONTROL PROGRAM

The DOMC was established in 2000 as the operational arm of the National Malaria Control Program, and falls under the Promotive and Preventive Health Services Department under the Director of Medical Services. There are currently about 46 officers working in various technical groups with the division. A Malaria Business Plan has been prepared by DOMC for support by the GOK and development partners. It was developed based on the National Malaria Strategy as well as National Health Sector Strategic Plan II, and includes seven priority sections: program administration and coordination; clinical management to provide prompt effective treatment; management of malaria and anemia in pregnancy; vector control; epidemic preparedness and response; information, education and communication; monitoring, evaluation and research. The DOMC has assigned lead officers for each priority section. The resource requirements outlined for 2006-2007 are \$100 million.

In addition to DOMC, other key departments within the MOH for malaria include the Division of Child Health and the Immunization program, DRH, and the Division of Environmental Health. The DOMC is also responsible for coordinating with KEMSA and MEDS on malaria drug procurement and distribution, and with the Pharmacy Division, and the Pharmacy and Poisons Board, the MOH's Drug Regulatory Authority. DOMC staffs also coordinate closely with the staff within the MOH responsible for the overall HMIS. Due to the more stringent requirements of the DOMC to monitor progress and report to partners such as the GFATM, an M&E unit was established within the Division.

DOMC staffs have been stretched considerably by the substantial workload involved in reporting on the GFATM grants, and by the additional workload related to collecting AL consumption data, as well as overseeing the effective implementation of the AL roll-out nationwide. The DOMC is also responsible for managing the very ambitious IRS program in 16 epidemic-prone districts, covering a significant share of the population.

Proposed USG Activities: (No additional funding-covered under other sections)

Under the PMI, the USG will provide additional support to the MOH and specifically to the DOMC. This support is critical to the effective implementation of PMI activities, and the long-term institutional capacity building of the DOMC and the MOH. Specifically, this support will include:

- 1. One of the primary roles for the PMI in-country staff will be to work closely with their counterparts in the DOMC. These staff will be expected to spend a significant portion of each day with the DOMC, and would be expected to have a desk or a place to work within the DOMC in order to effectively integrate this team with the DOMC staff.
- 2. Continuation of technical assistance for the M&E unit within the DOMC.
- 3. Technical support for the overall effective implementation of Kenya's IRS program, in addition to the focused implementation of IRS in the four districts described in the IRS section.
- 4. Support for oversight and supervision particularly of the AL roll out, as well as support for meeting the reporting requirements of the DOMC.

COMMUNICATION AND COORDINATION

There are a number of very active partners in malaria control in Kenya, including research institutions, NGOs, WHO, the private sector and development partners. These partners work closely with the DOMC and each other through both formal and informal structures.

There is a malaria subgroup under the Interagency Coordination Committee for the GFATM. The malaria ICC is convened by the head of the DOMC on behalf of the Director of Medical Services. The malaria ICC includes the MOH, NGOs, FBOs, the private sector and development partners.

There are also several working groups led by the DOMC around particular issues. These include the Drug Policy Technical Working Group, which was reconvened to help affect Kenya's drug policy change. There is also a formal IEC working group which comprises representatives from various departments of the MOH and stakeholders to assist in the implementation of the IEC strategy and plan. Stakeholders and partners also convene around ITNs and other vector control issues.

The NGO sector has organized itself under the umbrella of an association known as the Kenya NGO Alliance Against Malaria (KeNAAM). KeNAAM was established in 2001 and includes both national and international NGOs working on malaria in Kenya as well as development partners and the MOH. The purpose of KeNAAM is to enhance collaboration through networking and to improve collaboration among the NGOs and with public sector and donor partners. KeNAAM has over 42 members.

In addition, the major bilateral donors working in Kenya have come together to develop a Joint Programme of Work for their health programs in Kenya. Early in 2007, six donors (Danish DANIDA; UK DfID; German Development Cooperation; Swedish SIDA; the US Government; and the World Bank) participated in the development of a framework for coordination and action within the health sector. Under this framework, each partner is to select relevant priority areas and provide funding in a coherent and coordinated way, respecting the leadership and stewardship of the MOH. It is anticipated that funding provided by these 6 partners will fall under the auspices of this framework and be coordinated within it.

NGO COLLABORATION

Current Status

In addition to the contributions of USG agencies, and multilateral and bilateral organizations, several international NGOs are active in malaria control in Kenya. KeNAAM was established in 2001 and includes both national and international NGOs working on malaria in Kenya. The purpose of KeNAAM is to enhance collaboration through networking and to improve collaboration among the NGOs and with public sector and donor partners. KeNAAM has over 42 members. In addition, USAID/Kenya is currently supporting the APHIA II projects across the eight provinces to provide integrated HIV/AIDS services with limited FP/RH/CS components. The projects are implemented through various consortia comprised of partnerships between international and local NGO and CBOs.

Proposed USG Activities

Under the FY2008 PMI plan, a number of community-based, health-facility based, and central level activities are planned with NGOs, including: training and capacity building of the NMCP; training of health care providers; activities to raise awareness and knowledge in the community about malaria prevention and treatment. Specific activities will include:

- 1. Community-based and facility-based training and IEC/BCC activities for MIP through the network of NGOs in the APHIA partners (\$1,100,000, see MIP)
- 2. Development of training materials and preservice curriculum development for MIP and case management through JHPIEGO (\$150,000, see MIP and Case Management)
- 3. IEC/BCC activities for promotion of proper use of LLINs in a newly competed RFA for NGOs/FBOs/CBOs (\$800,000, see Vector Control, ITNs)

STAFFING AND ADMINISTRATION

Two new health professionals will be hired to oversee the PMI in Kenya, one representing CDC and one representing USAID. In addition, one or more FSNs will be hired to support the PMI team. All PMI staff members will be part of a single inter-agency team led by the USAID Mission Director or his/her designee in country. The PMI team will share responsibility for development and implementation of PMI strategies and work plans, coordination with national authorities, managing collaborating agencies and supervising day-to-day activities. Candidates for these positions will be evaluated and/or interviewed jointly by USAID and CDC, and both agencies will be involved in hiring decisions, with the final decision made by the individual agency.

It is envisioned that these two PMI professional staff will work together to oversee all technical and administrative aspects of the PMI in Kenya, including finalizing details of the project design, implementing malaria prevention and treatment activities, monitoring and evaluation of outcomes and impact, and reporting of results. Both staff members will report to the USAID Mission Director or his/her designee. The CDC staff person will be supervised by CDC, both technically and administratively. All technical activities will be undertaken in close coordination with the MoH/NMCP and other national and international partners, including the WHO, DfID, the GFATM, World Bank and the private sector.

Locally-hired staff to support PMI activities either in Ministries or in USAID will be approved by the USAID Mission Director. Because of the need to adhere to specific country policies and USAID accounting regulations, any transfer of PMI funds directly to Ministries or host governments will need to be approved by the USAID Mission Director and Controller.

Proposed USG Component: (\$1,665,000)

<u>In-country PMI staff salaries, benefits, travel and other PMI administrative costs</u>: Two expatriate PMI staff members to oversee activities supported by the Initiative in Kenya will be recruited and hired by CDC and USAID. The recruitment for the USAID position will be

initiated in the summer of 2007 with FY07 malaria funds, with the CDC position recruitment and hiring following immediately thereafter once early FY08 PMI funds have been made available. One FSN will be recruited early in FY08. (\$1,665,000)

ANNEX 1

Table 1

President's Malaria Initiative – Kenya Year 1 (FY08) Timeline of Activities

2007		2008										
OCT- DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEPT	OCT	NOV	DEC
ITNs				Micro- scopes		SP & ACTs & severe malaria drugs						
	OCT- DEC	OCT- JAN DEC	OCT- JAN FEB DEC	OCT- JAN FEB MAR DEC	OCT-DEC JAN FEB MAR APR ITNs Micro-	OCT-DEC JAN FEB MAR APR MAY ITNs Micro-	OCT-DEC JAN FEB MAR APR MAY JUN ITNS Microscopes SP & ACTs & severe	OCT-DEC JAN FEB MAR APR MAY JUN JUL ITNs Microscopes SP & ACTs & severe malaria	OCT-DEC JAN FEB MAR APR MAY JUN JUL AUG ITNs Microscopes ACTs & severe malaria	OCT-DEC JAN FEB MAR APR MAY JUN JUL AUG SEPT Microscopes Microscopes SP & ACTs & severe malaria	OCT-DEC JAN FEB MAR APR MAY JUN JUL AUG SEPT OCT ITNs Microscopes SP & ACTs & severe malaria	OCT-DEC JAN FEB MAR APR MAY JUN JUL AUG SEPT OCT NOV ITNs Microscopes ACTs & severe malaria

ITINI OD 1							
ITN OR study							
Conduct ITN							
OR study							
IRS- planning							
and							
environmental							
activity							
IRS							
Environmental;							
Assess							
Purchase IRS							
equip/insect.							
IRS							
implementation							
IRS							
Surveillance							
Evaluation of							
duration of							
non-pyrethroid							
insecticides							
ACT training							
Preservice							
curriculum				1			
development							
Laboratory							
needs							
assessment							
Laboratory							
technician							
training							
Pilot RDTs							
Technical							
assistance for							
assistance for							

ACT quantification							
quantification							
DHS							
HMIS support							
Insecticide							
resistance monitoring							
monitoring							

Table 2

President's Malaria Initiative – Name of Country
Planned Obligations for FY08 (USD)

Proposed Activity	Mechanism	Budget (commodities)	Geographic Area	Description of Activity	Page Number Reference
		PREVENTI	VE ACTIVITIES		
SP procurement	DELIVER	\$110,000 (<i>\$110,000</i>)	Nationwide	Procurement of 840,000 doses of SP for IPTp	
*Community Training and IEC	APHIA	\$90,000	17 districts in Nyanza and Western Province	Training of 5100 community health care workers in MIP/FANC and IEC activities	
HCW training at facilities	APHIA	\$1,010,000	29 districts	Training of facility and community-level health care workers in MIP/FANC and IEC activities	
Printing and distribution of materials	JHPIEGO	\$50,000	Nationwide	Printing and Distribution of FANC/MIP materials developed by JHPIEGO/DRH	
Purchase of LLINs	PSI	\$4,600,000 (\$ <i>4,200,000</i>)	Nationwide	Purchase of 600,000 LLINs to fill in annual gap, and program support	
BCC for ITN usage	New RFA for NGOs/FBOs	\$915,000	Nationwide	Community BCC/IEC messaging to encourage proper use	
Organization/planni ng for retreatment program	PSI	\$375,000 (\$350,000)	Nationwide	Support for retreatment/replacem ent campaign	
IRS implementation and management	RTI	\$3,500,000 (\$ <i>700,000</i>)	2 epidemic- prone, 2 endemic districts	Support for move to IRS in endemic areas, and the bordering epidemic-prone districts	
TA for IRS	RTI/CDC	\$225,000/ \$25,000	4 districts	TA for implementation of IRS and environmental assessment including two TA visits from CDC entomology staff	

Sentinel site	UNC Aphia II	\$200,000	2-4 districts	Support of existing	
Roll-out of HMIS registers	TBD	\$50,000	Nationwide	Printing and distribution of health information registers	
Case Mgmt.		(\$4,620,000) MONITORING	AND EVALUAT	TON	
SUBTOTAL:		\$6,200,000			
RDT Pilot	CDC/DELIVE R	\$200,000 (\$ <i>120,000</i>)	2 districts	Pilot use of RDTs for malaria diagnosis in 2 districts	
Purchase of microscopes	Walter Reed	\$200,000 (\$2 <i>00,000</i>)	Nationwide	Purchase of microscopes for facilities where trainees came from	
training				technicians in malaria diagnosis	
assessment Lab technician	Walter Reed	\$12,500 \$120,000	Nationwide	diagnostic capacity of health facilities including one TA visit from CDC Atlanta Training of 80 lab	
TA for supply chain management Diagnostic needs	SPS MCDI/CDC	\$540,000 \$87,500/	Nationwide Nationwide	TA for ACT distribution and quantification Assessment of	
Pre-service curriculum development	JHPIEGO	\$100,000	Nationwide	Pre-service curriculum development for ACT and MIP policy and practices	
Training	SPS	\$640,000	Nationwide	Training for treatment policy role-out	
Purchase Coartem and severe malaria drugs	DELIVER	\$4,300,000 (\$4,300,000)	EMENT ACTIVITED Nationwide	Purchase of Coartem and severe malaria drugs to help fill annual gap	
Preventive		(\$5,360,000)			
Insecticide resistance monitoring SUBTOTAL:	CDC/KEMRI	\$100,000 \$11,225,000		Support for monitoring of insecticide resistance	
alternatives pyrethroids		\$100,000		use of non-pyrethoid for IRS to prevent resistance	
Surveillance Pilots for	WHO/CDC ³ CDC ³	\$75,000/ \$100,000 \$50,000	4 districts	Surveillance of malaria morbidity in IRS districts Pilot to examine the	

_

³ See TDY table for cost of two visits from CDC/Atlanta staff

support	Evaluation			sentinel sites	
DHS support	MACRO	\$300,000	Nationwide	Support of malaria portion of DHS	
HMIS support	SPS	\$237,500/ \$12,500	Nationwide	Support of reporting and supervision at health facilities including one TA visit from CDC Atlanta	
Investigation of causes of deaths from health facilities relative to DSS	CDC/KEMRI	\$75,000	District-level, population of 135,000	Measure of impact indicators and validation of other data sources	
Monitoring and Evaluation System Strengthening Tool	UNC Aphia II Evaluation	\$35,000	Nationwide	Stakeholders meeting utilizing new RBM initiative tool to develop a country- specific M&E plan	
SUBTOTAL: M&E		\$910,000			
	IN-COUN	TRY MANAGEN	IENT AND ADM	INISTRATION	
In-country staff; Admin. expenses SUBTOTAL: Mgmt. and Admin.	USAID/CDC SPS	\$1,400,000 \$265,000 \$1,665,000	Nairobi	Support in-country staff to support PMI	
		0	THER		
SUBTOTAL: Other					
GRAND TOTAL		\$20,000,000 (\$9,980,000)	Commodities	represent 49.9% of to	tal budget

^{*}Note: the order of activities under each sub-heading in this table should be the same as that in the text.

Table 3

KENYA – Year 1 Targets **Assumptions and Estimated Year 1 Coverage Levels**

Assumptions:

Population of country (estimated) at risk for malaria: 23 million

Pregnant women: 4.5% of total population = 1.1 million pregnant women

Infants (children <1): 3% of population = 690,000 infants.
Children <5: 16% of population = 3.7 million children under five

Average number of malaria-like illnesses per year and cost per treatment (costs given are for artemether-lumefantrine):

Children <5 (2.5 episodes /year): 9.25 million illnesses/year at \$0.50 each Older children (1.5 episodes/year): 7.5 million illnesses/year at \$1.50 each

Adults (1.0 episodes/year): 14.3 million illnesses/year at \$2.00 each (assume that the PMI will cover only one-third

of adult episodes)

Cost of a LLIN = \$7.00; average of 2.5 nets/household needed to cover all pregnant women and children under five in family

Cost of spraying a house with an average of 5-6 inhabitants = \$15.00

Intervention	Needs for 100% Nationwide Coverage over 3 Years*	Needs for 85% Nationwide Coverage over 3 Years*	Annual Needs to Achieve 100% Coverage	Needs to Achieve Year 1 PMI Targets	Year 1 Contributions
ІРТр	1.1 million pregnant women x 2 treatments/woman = 2.2 million treatments/year x 3 years = 6.6 million treatments	5.6 million SP treatments	2.2 million SP treatments	Target: 50 % of pregnant women receive 2 doses of IPT = 1.1 million	List here contributions in terms of funding or commodities from different partners and the PMI and any remaining gap: PMI, 840,000 doses; GFATM 280,000
LLINS	4,6 million households x 2.5 nets/household = 11.5 million nets	9,975,000 LLINs (or 3,260,000 nets per year for 3 yrs)	3,835,000 LLINs	Target: 50-60% of children under 5 and pregnant women sleep under LLIN	GFATM 1.0 million LLINs, DfID million LLINs
ACTs – children < 5	3.7 million children under 5 x 2.5 episodes/year = 9.25 million treatments/year x 3 years = 27.8 million	9.25 million x 85% = 7.9 million treatments x 3 yrs = 23.6 million	9.25 million treatments	Target: _85% of children under 5 and older children receive ACTs, or 11.2 million treatments	GFATM funded treatments for Year 1 equals 12 million treatments of which 80% are for under 5's and older children (9.6 million treatments)
ACTs – older children	5.0 million older children x 1.5 episodes/year = 7.5_ million treatments/year x 3 years= 22.5 million	7.5 million x 85% = 6.4 million tx x 3 yrs. = 19,2 million	7.5 million treatments		PMI funded treatments for Year 1 equals 1.8 million treatments of which 90% are estimated for under 5's and
ACTs - adults	14.3 million adults x 1 episodes/year x. = 14.3 million treatments/year x 3 years = 42.9 million	14.3 million x 85% = 12.2 million tx x 3 yrs. = 36.9 million	14.3 million treatments		older children (1.6 million treatments)Therefore, 85% of ACT needs for children under 5 and older children are met in
ACTs TOTAL	729.5 million treatments	79.7 million treatments			Year 1
IRS			233,000 households	Target: 85% of targeted houses to be sprayed (198,000 households)	

Table 4

President's Malaria Initiative – Name of Country
Year 1 (FY08) Budget Breakdown by Intervention (USD)

Area	Commodities \$ (%)	Other \$ (%)	Total \$
Insecticide-treated Nets	\$4,550,000 (77%)	\$1,340,000 (23%)	\$5,890,000
Indoor Residual Spraying	\$700,000 (15%)	\$3,425,000 (85%)	\$4,050,000
Case Management	\$4,620,000 (71%)	\$1,795,000 (29%)	\$6,200,000
Intermittent Preventive Treatment	\$110,000 (9%)	\$1,150,000 (91%)	\$1,260,000
Epidemic Preparedness & Response			
Monitoring and Evaluation		\$910,000 (100%)	\$910,000
Administration		\$1,665,000 (100%)	\$1,665,000
Total	\$9,980,000 (50%)	\$10,020,000 (50%)	\$20,000,000

Table 5
Year 1 (FY08) Budget Breakdown by Partner (USD)

(Once the FY08 Implementation Plan is approved and contracts/grants cooperative agreements awarded, all other partners will be listed here)

Partner Organization	Geographic Area	Activity	Budget
DOMC/SPS	Nationwide	ACT policy role-out, supply chain management TA, and HMIS TA	\$1,682.500
WHO	-	Case surveillance in IRS districts	\$75,000
CDC	-	TA for vector control, diagnostics, M&E, and OR support for pilot for alternative pyrethroids and surveillance	\$200,000
CDC/DELIVER	2 districts	RDT pilot including procurement of RDTs	\$200,000
CDC/KEMRI		Insecticide resistance monitoring	\$175,000
RTI	4 districts	IRS implementation, management, and TA	\$3,725,000
JHPIEGO	Nationwide	Development of training materials and curriculum	\$150,000
Walter Reed	Nationwide	Laboratory technician training and procurement of microscopes	\$320,000
PSI	Nationwide	Procurement and distribution of LLINs, and program support	\$4,975,000
APHIA	46 districts	MIP training	\$1, 100,000
UNC APHIA II	Nationwide	Sentinel site establishment and MESST meeting	\$235,000
MACRO	Nationwide	DHS and laboratory needs assessment	\$300,000
DELIVER	Nationwide	Procurement of drugs	\$4,410,000
MCDI	Nationwide	Laboratory needs assessment	\$87,500
TBD	Nationwide	Roll-out of HMIS registers	\$50,000
New RFA for NGO/FBO	Nationwide	Community BCC/IEC	\$915,000
USAID/CDC	Nairobi	Staffing for 2 positions	\$1,400,000
Total			\$20,000,000

Annex 2

Three Year Strategy and Plan: Kenya

GOAL AND TARGETS OF THE PRESIDENT'S MALARIA INITIATIVE (by 2010)

By the end of the program, reduce malaria-related mortality in Kenya by 50% compared to pre-Initiative levels.

By the end of 2010, in collaboration with other partners, PMI will have assisted Kenya to achieve the following targets in populations at risk for malaria:

- More than 90% of households with a pregnant woman and/or children under five will own at least one ITN:
- 85% of children under five will have slept under an ITN the previous night;
- 85% of pregnant women will have slept under an ITN the previous night;
- 85% of houses in geographic areas targeted for IRS will have been sprayed;
- 85% of pregnant women and children under five will have slept under an ITN the previous night or in a house that has been sprayed with IRS in the last 6 months;
- 85% of women who have completed a pregnancy in the last two years will have received two or more doses of IPTp during that pregnancy;
- 85% of government health facilities have ACTs available for treatment of uncomplicated malaria; and
- 85% of children under five with suspected malaria will have received treatment with ACTs in accordance with national malaria treatment policies within 24 hours of onset of their symptoms.

PREVENTION ACTIVITIES

Control of malaria in pregnant women:

Each year there are approximately 1.6 million pregnancies in Kenya, with over 1.1 million of those at risk of acquiring malaria infection. The approach adopted in Kenya to meet the malaria in pregnancy targets includes several components. The core of the program is centered on scaling up Focused Antenatal Care (FANC) approach to promote the health of pregnant women, which includes a recommendation that pregnant women make at least 4 visits, beginning in the 1st trimester, to a skilled provider during their pregnancy. Prevention of MIP has been incorporated as an integral component of the FANC approach. National policy calls for free dose of SP at each ANC visit after the first trimester. FANC with MIP interventions is being rolled out through nation-wide training of health providers at health facilities and among community health workers.

This training is being complemented by community based communication aimed at women and their families to ensure women access ANC services early enough in their pregnancy to get at least two doses of SP.

The third component of the national strategy is ensuring pregnant women access and use ITNs.

For Year 1 of the PMI, some of the SP is being purchased with GFATM grant resources. SP is distributed by KEMSA to health facilities. An estimated 2.2 million doses of SP are needed each year to provide the minimum of 2 doses per pregnant woman.

In Years 1, 2 and 3, PMI will purchase SP to help fill the commodity gap. Investments in improving KEMSA's ability to deliver commodities will also contribute to reducing stockouts of SP. In conjunction with the Division of Reproductive Health and the Division of Malaria Control, in Year 1, PMI will help complete the FANC/MIP training at the facility level and begin community level training. In subsequent years, PMI will support refresher training and fill in future training gaps at the facility level and scale-up community level involvement. As a result of the combined efforts of the MOH, other partners and PMI, all facilities will have staff trained in FANC and MIP by the end of Year 3 of the PMI.

The community level training begun in Year 1 will be continued through all three years of PMI and be complemented by community based IEC through NGOs to help ensure women access ANC services early in their pregnancy and sleep under an ITN. PMI's support for ITN distribution will also increase the number of women sleeping under an ITN.

Insecticide treated nets (ITNs)

The MOH National Malaria Strategy (2001-2010) includes the use of ITNs by at risk communities. The MOH, working with partners including NGOS, CBOs, FBOs, the commercial sector and bilateral and multilateral organizations, promotes a whole market approach to distribute ITNs to biologically and economically vulnerable populations. The MOH with support from WHO and DFID is currently revising its strategic framework for ITNs.

Considerable progress has been made recently in increasing access to ITNs – with coverage rates close to 50% in most endemic districts, the foundation for achieving the ITN targets is very good in Kenya. The DOMC estimates between 3-5 million nets per year will be needed over the next few years, including distribution through ANC clinics, replacement ITNs, and ITNs for the economically vulnerable and other vulnerable groups. Currently, ITNs are provided by the GFATM grant, funding from DfID and in the future, from PEPFAR, however there are gaps in meeting the required needs. In Year 1, PMI will purchase about 650,000 million LLINs, including LLINs for replacing some of the conventional nets currently being used. Over the next three years, PMI will purchase at least 650,000 LLINs each year. No retreatment kits are needed since DfID

will purchase kits for a retreatment campaign planned for November 2007; the MOH would like to then transition to a full replacement of these conventional nets over time.

In addition to the purchase and assistance with delivery of ITNs, PMI will also support a community based IEC/behavior change effort working with NGOs to encourage appropriate use of ITNs by vulnerable groups and to reach the targets of 85% of children under-five and pregnant women sleeping under an ITN. This behavior change effort will continue throughout the PMI. Overall, the ITN interventions will be closely linked with malaria in pregnancy interventions.

Indoor residual spraying:

Using support from the Global Fund, the MOH is currently implementing IRS in 16 epidemic prone highland districts in western Kenya. The total population in these areas is approximately 6.5 million people living in approximately 1.3 million household units. The spraying is coordinated at the district level where there was little capacity to properly plan, manage and evaluate the IRS. In Year 1, PMI will provide comprehensive assistance for IRS in two of these districts, and support IRS in two bordering endemic districts. PMI will also provide management support to the implementation of IRS in all districts. In Years 2 and 3, PMI will continue to provide technical and management support for the implementation of IRS, and support insecticide resistance monitoring in districts with IRS coverage and in districts with high coverage of ITNs. PMI will also continue to support IRS in the selected endemic district(s), and use information from this experience to work with the DOMC and MOH to implement and target IRS efforts in the future. Implementing partners will include the DOMC, district health teams, and the Research Triangle Institute (RTI).

IRS interventions will be monitored by the DOMC and RTI, with data collected on households covered. In addition, PMI will support DOMC's surveillance efforts in IRS districts to plan for future spray rounds and expansion into new endemic districts.

CASE MANAGEMENT

In April 2005, Kenya began to put in place its new first line treatment policy, which is in the early stages of implementation. This policy recommends artemether-lumefantrine (AL) as the first-line therapy for uncomplicated malaria cases. With resources from the GFATM, Kenya has resources to purchase a substantial portion of its AL requirements through 2011. However, currently there appear to be supply gaps for AL, and insufficient resources to establish a buffer stock.

As part of the comprehensive roll out strategy, with resources from the Global Fund and from DfID channeled through WHO, Kenya is in the midst of rolling out training for all health facilities in the application of the new treatment policy. KEMSA and MEDS have joint responsibility for procuring and distributing antimalaria drugs and other medicines to the public and mission-sector health facilities respectively. Both agencies are committed to ensuring effective distribution of antimalarial drugs to their facilities.

KEMSA is also receiving support from several different sources to build their capacity to deliver and manage commodities.

Current policy in Kenya is for children under 5 with fever or a history of fever to be treated presumptively for malaria. For older children and adults a parasitological diagnosis through microscopy or the use of an RDT is recommended. A health facility survey completed several years ago in four representative endemic districts found that 57% of health facilities below the district level did not have the ability to perform microscopic diagnosis of malaria.

Over the next three years, the PMI will work closely with the DOMC, District Health Management Teams, KEMSA, MEDS, WHO and other partners to ensure the effective national implementation of Kenya's malaria treatment policy. This will include purchase of ACTs and severe malaria drugs as needed to fill gaps; completion of training for all health facilities; work with medical and nursing schools to ensure preservice curricula reflect the appropriate treatment approaches; and provide targeted technical assistance to ensure the effective management and distribution of antimalaria treatment.

For diagnosis, the PMI will work with the DOMC, WHO and other partners to finalize the development of a diagnostic policy, and help to implement that policy. Results from the RDT pilot launched in Year 1 will provide input to that policy. Using results of a comprehensive laboratory needs assessment to be undertaken in Year 1, in Years 2 and 3, PMI will continue to strengthen laboratory and microscopy capacity through training of laboratory technicians and procurement of microscopes and reagents.

EPIDEMIC SURVEILLANCE AND RESPONSE

Epidemic surveillance and response will be a focus of PMI involvement in Kenya. PMI will concentrate on supporting Federal, Regional and district efforts to implement effective ESR and ensure judicious use of commodities for these situations. PMI will assist in monitoring of the situation to ensure that all levels will be able to respond appropriately. Managing and strengthening information and surveillance systems will be an important component to monitoring epidemics and ensuring timely responses. PMI will also consult with other in-country malaria partners to ensure implementation of the long-term strategy for epidemic surveillance and response.

MONITORING AND EVALUATION

The 2007 Malaria Indicator Survey (MIS) will provide information that will be used as baseline for coverage indicators for the PMI in Kenya. The 2008 DHS survey will provide estimates in malaria coverage and provide baseline estimates of all cause mortality and malaria-specific mortality for children under age five-years. PMI will support a follow up MIS in 2011 to document changes in coverage with malaria interventions and impact on malaria burden. Two existing DSS sites will be used to consider the potential for tracking of malaria related mortality in health facilities.

PMI will provide on-going support to the MOH to improve the implementation and roll-out of the Health Management Information System, particularly to ensure the HMIS collects key malaria indicators. PMI will support this roll-out in all three years. PMI will also provide support to put in place effective insecticide resistance monitoring in conjunction with CDC/KEMRI. Implementing partners for each activity will also be asked to provide routine monitoring information on program progress.

SUSTAINABILITY PLAN

The Kenya PMI plan is designed to foster sustainability for the program interventions. The two PMI malaria advisors will have office space at DOMC and will spend a significant portion of their time working with the Director of the DOMC and his staff to provide management and technical advice and assistance. This hands-on engagement will deepen the technical and managerial capacity of the DOMC. PMI will also provide other management and technical support to the DOMC. This includes continued technical support for implementation of the HMIS.

In addition, PMI will provide support to KEMSA to improve capacity for quantification of commodity requirements, and will also work with the Division of Reproductive Health to ensure effective and sustained collaboration between DRH and DOMC around malaria in pregnancy.

At the community level, PMI will work with district and community health workers to train and build their technical and management capacity. PMI will also work with local NGOs to build and sustain their capacity for delivering malaria services and messages.

PMI will not only support implementation of IRS in several districts, but will build the capacity at the DOMC and at the district level to plan, manage and implement effective IRS programs. This also includes building capacity to carry out insecticide resistance monitoring, and to adjust planning to respond to entomological and resistance data.

Financially, PMI will undertake advocacy with the Government of Kenya to encourage the GOK to take on increasing financial responsibility for the malaria program. PMI will also work with other donors and with the GOK to submit proposals to the GFATM for future funding. Work with the private sector is also an important component of PMI efforts in Kenya – this will be an important source of continued sustainable funding for the Kenya program.

STAFFING AND ADMINISTRATION

In Years 2 and 3, PMI will continue to support the two health professionals who were hired in Year 1 to oversee the PMI in Kenya, one representing CDC and one representing USAID. In addition, one or more FSNs will be hired to support the PMI team. All PMI staff members will be part of a single inter-agency team led by the USAID Mission Director or his/her designee in country. The PMI team will share responsibility for development and implementation of PMI strategies and work-plans, coordination with

national authorities, managing collaborating agencies and supervising day-to-day activities. Candidates for these positions will be evaluated and/or interviewed jointly by USAID and CDC, and both agencies will be involved in hiring decisions, with the final decision made by the individual agency.

It is envisioned that these two PMI professional staff will continue to work together to oversee all technical and administrative aspects of the PMI, including finalizing details of the project design, implementing malaria prevention and treatment activities, monitoring and evaluation of outcomes and impact, and reporting of results. Both staff members will report to the USAID Mission Director or his/her designee. The CDC staff person will be supervised by CDC both technically and administratively. All technical activities will be undertaken in close coordination with the MOH/DOMC and other national and international partners, including the WHO, UNICEF, the GFATM, WB, and the private sector.

Locally-hired staff to support PMI activities either in Ministries or in USAID will be approved by the USAID Mission Director. Because of the need to adhere to specific country policies and USAID accounting regulations, any transfer of PMI funds directly to Ministries or host governments will need to be approved by the USAID Mission Director and Controller.

Indicator	2003 Kenya DHS	Year 1	Year 2	Final Evaluation
Proportion of children under five years old with fever in the last two weeks who received treatment with an antimalarial according to national policy within 24 hours of onset of fever.	6%	40%	65%	85%
Proportion of women who have received two or more doses of IPTp during their last pregnancy in the last two years.	4%	50%	75%	85%
Proportion of households in malarious areas (70% of Kenya) with at least one ITN**	TBD	65%	80%	90%
Proportion of pregnant women in malarious areas who slept under an ITN the previous night**	TBD	50%	75%	85%
Proportion of children under fiver years old in malarious areas who slept under an ITN the previous night**	TBD	60%	75%	85%
Proportion of households in 2 targeted epidemic districts sprayed with IRS in the last year#	50%	85%	85%	85%
Proportion of households in 2 targeted endemic districts sprayed with IRS in the last year#	0%	85%	85%	85%

^{**} MIS to be conducted in July 2007
Baseline data from DOMC estimates

Table 2

Illustrative 3-Year Budget and Expected Coverage Levels

PMI Targets: After three years of full implementation, the PMI will achieve the following targets in populations at risk of malaria in Kenya:

- i. 85% of children under five will have slept under an ITN the previous night;
- ii. 85% of pregnant women will have slept under an ITN the previous night;
- iii. 85% of pregnant women will have received two or more doses of SP for IPTp during their pregnancy;
- iv. 85% of houses targeted for indoor residual spraying will have been sprayed;
- v. 85% of children under five with suspected malaria will have received treatment with ACTs drug in accordance with national malaria treatment policies within 24 hours of the onset of their symptoms.

Assumptions:

Assumptions:

Population of country (estimated) at risk for malaria: 23 million

Pregnant women: 4.5% of total population = 1.1 million pregnant women

Infants (children <1): 3% of population = 690,000 infants

Children <5: 16% of population = 3.7 million children under five

Average number of malaria-like illnesses per year and cost per treatment (costs given are for artemether-lumefantrine):

Children <5 (2.5 episodes /year): 9.25 million illnesses/year at \$0.50 each Older children (1.5 episodes/year): 7.5 million illnesses/year at \$1.50 each Adults (1.0 episodes/year): 14.3 million illnesses/year at \$2.00 each (assume that the PMI will cover only one-third of adult episodes)

Cost of a LLIN = \$7.00; average of 2.5 nets/household needed to cover all pregnant women and children under five in family

Cost of spraying a house with an average of 5-6 inhabitants = \$15.00

Item/Activity	Annual Cost per Person	Annual Cost	3-Year Total	Assumptions/Comments
Prevention – insecticide-treated nets		\$6,400,000	\$18,200,000	23 million population at risk of malaria = 4.6 million households x 2.5 nets/household x 85% coverage -6.5 million (10.8 x 60%) ITNs distributed since 2002 – 1.0 million committed by GFATM in next year – 1.4 million committed by DfID in next year x \$7.00/net
Prevention – indoor residual spraying		\$6,000,000	\$18,000,000	IRS will target 1,200,000 households or 6,000,000 people at \$14.00 per household, doubling each year
Treatment – malarial illnesses		\$37,800,000	\$113,400,000	Children under 5, 3.7million x 2.5 episodes/year x 85% = 4.6 m x \$.50 = 3.9 m; Older children 5.0 x 1.5 episodes/year x 85% x \$1.50 = 9.6; 14.3 m adults x 1.0 episode/year x 85% x \$2.00 = 24.3
Treatment – IPT for pregnant women		\$187,000	\$561,000	1.1 million pregnant women x \$0.20 per year x 85% coverage
Epidemic Preparedness				
Implementation Support	\$0.92	\$21,600,000	\$64,800,000	Commodity management, human resources, supervision, training, social mobilization, etc
Monitoring and Evaluation		\$1,430,000	\$3,430,000	Directly from Kenya PMI M&E budget, assuming no cost sharing by other donors, one time cost of DHS at 300,000 and project end MIS at 1,300,000
Cost of Program		64,369,500	\$218,391,000	

USG Implementation Support Costs	\$1,400,000	\$4,200,000	Long-term expatriate advisors' salaries, benefits, travel; local staff; office supplies and equipment for PMI in-country office; TDY from CDC and USAID
Total funding needed (including USG	\$65,839,500	\$222,591,000	
program costs)			
Government of Kenya malaria budget	\$0.0	\$0.0	Costs covered in GFATM Rd 2 and Round 4. The GoE applied for GF Rd 7
GFATM Rd 2 and Rd 4 Phase 1 approved funding		\$23, 059, 930	Round 2: Lifetime Budget of \$27,700,377 out of which 4,640,447 has been disbursed
		\$29,560,787	Round 4: grant totals \$186,096,553. Phase 1 totaling \$81,749,756 has been approved, and \$52,188,969 disbursed
DfID		\$19,000,000	Approximately 19.0 million for ITNs
Available funding from other sources		\$71,620,717	
PMI funds available (estimated):			Assumes PMI funding is divided between countries based roughly on their populations
Year 1	\$20,000,000		Assumes 15 PMI countries
Year 2	\$20,000,000		Assumes 15 PMI countries
Year 3	\$30,000,000		Assumes 15 PMI countries
Years 1 through 3		\$70,000,000	
Total Available funding		\$141,620,717	
Remaining Gap		\$80,970,283	3-year shortfall to meet total need